US009682224B2

(12) **United States Patent**
Downing et al.

(10) **Patent No.: US 9,682,224 B2**
(45) **Date of Patent: Jun. 20, 2017**

(54) **METHOD AND SYSTEMS FOR PROVIDING FLUID COMMUNICATION WITH A GASTROSTOMY TUBE**

(71) Applicant: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(72) Inventors: **Anthony Downing**, Ayer, MA (US); **James Wilkie**, Melrose, MA (US); **Ronald Court**, Pelham, NH (US); **Steven Jacques**, Westford, MA (US); **Michael W. Gauderer**, Salem, SC (US)

(73) Assignee: **C. R. Bard, Inc.**, Murray Hill, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 251 days.

(21) Appl. No.: **14/507,801**

(22) Filed: **Oct. 6, 2014**

(65) **Prior Publication Data**

US 2015/0025476 A1 Jan. 22, 2015

Related U.S. Application Data

(63) Continuation of application No. 11/629,724, filed as application No. PCT/US2005/023297 on Jun. 29, 2005, now Pat. No. 8,858,533.
(Continued)

(51) **Int. Cl.**
A61M 25/16 (2006.01)
A61M 25/18 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61M 39/10*** (2013.01); ***A61J 15/0015*** (2013.01); ***A61J 15/0053*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61J 15/0015; A61J 15/0092; A61J 15/0053; A61M 2039/1077;
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,719,428 A 7/1929 Friedman
2,230,226 A 2/1941 Auzin
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0930083 A2 7/1999
EP 1623693 A1 2/2006
(Continued)

OTHER PUBLICATIONS

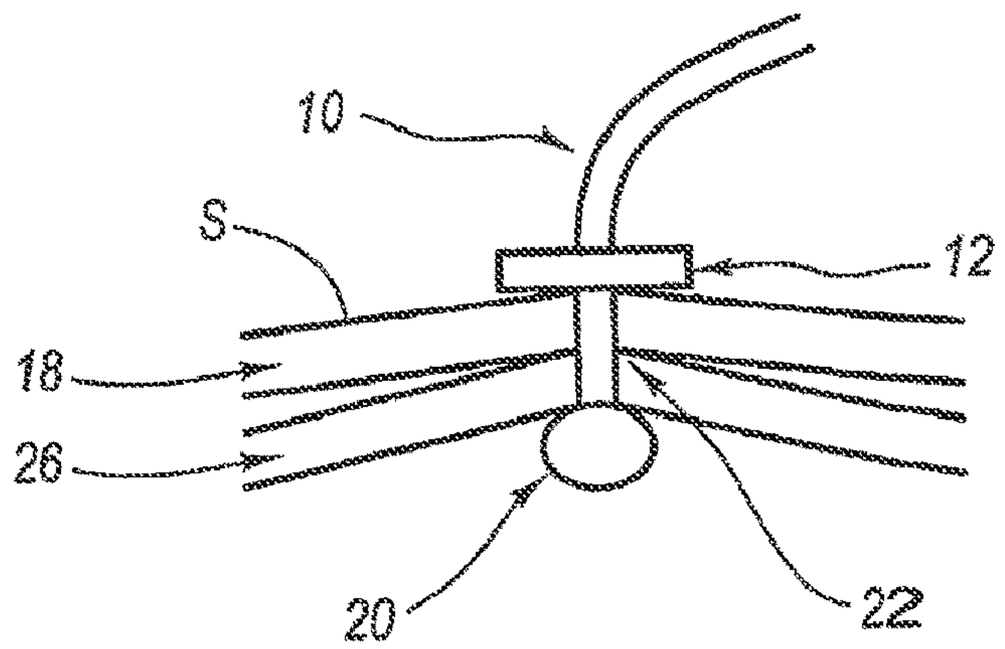
JP 2012-057330 filed Mar. 14, 2012 First Office Action dated Jan. 28, 2016.
(Continued)

Primary Examiner — Rebecca E Eisenberg
(74) *Attorney, Agent, or Firm* — Rutan & Tucker, LLP

(57) **ABSTRACT**

A low profile adaptor is disclosed to reduce the length of a gastrostomy tube that has been inserted by means of conventional endoscopic procedures or with a replacement feeding tube inserted into the patient's stomach. The gastrostomy tube is cut to the appropriate length by the physician. The adaptor comprises a stem which is inserted into the open end of the gastrostomy tube. The valve assembly contains a seal that functions as a one-way valve to prevent reflux of gastric contents but permits the introduction of feeding solution into the feeding tube. A lock and key mechanism is incorporated into the hub of the gastrostomy tube to prevent disconnection of the feeding tube. A cover is placed over the opening of the adapter to prevent contamination of the lumen of the gastrostomy tube.

8 Claims, 19 Drawing Sheets



Related U.S. Application Data

(60) Provisional application No. 60/583,703, filed on Jun. 29, 2004.

(51) **Int. Cl.**

A61M 39/02	(2006.01)
A61M 39/10	(2006.01)
A61M 39/12	(2006.01)
A61M 39/24	(2006.01)
A61J 15/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61J 15/0092*** (2013.01); ***A61M 39/1011*** (2013.01); ***A61M 39/12*** (2013.01); ***A61M 39/24*** (2013.01); *A61M 2039/1077* (2013.01); *A61M 2039/242* (2013.01); *A61M 2039/2426* (2013.01)

(58) **Field of Classification Search**

CPC A61M 2039/242; A61M 2039/2426; A61M 39/10; A61M 39/12; A61M 39/24; A61M 39/1011

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,108,595	A	10/1963	Overment
3,111,930	A	11/1963	Zipper
3,241,514	A	3/1966	Grimland
3,397,699	A	8/1968	Kohl
3,543,759	A	12/1970	McWhorter
3,692,029	A	9/1972	Adair
3,731,691	A	5/1973	Chen
3,915,171	A	10/1975	Shermeta
4,016,885	A	4/1977	Bruner
4,043,338	A	8/1977	Homm et al.
4,134,407	A	1/1979	Elam
4,143,651	A	3/1979	Patel
4,177,815	A	12/1979	Patel
4,227,293	A	10/1980	Taylor
4,245,639	A	1/1981	La Rosa
4,246,896	A	1/1981	Horne, Jr. et al.
4,366,708	A	1/1983	Warihashi
4,370,982	A	2/1983	Reilly
4,398,542	A	8/1983	Cunningham et al.
4,535,757	A	8/1985	Webster, Jr.
4,583,917	A	4/1986	Shah
4,592,747	A	6/1986	Pool
4,606,347	A	8/1986	Fogarty et al.
4,608,965	A	9/1986	Anspach, Jr. et al.
4,617,015	A	10/1986	Foltz
4,666,433	A	5/1987	Parks
4,685,901	A	8/1987	Parks
4,701,163	A	10/1987	Parks
4,729,706	A	3/1988	Peterson et al.
4,744,788	A	5/1988	Mercer, Jr.
4,795,430	A	1/1989	Quinn et al.
4,798,592	A	1/1989	Parks
4,863,438	A	9/1989	Gauderer et al.
4,872,483	A	10/1989	Shah
4,929,236	A	5/1990	Sampson
4,944,732	A	7/1990	Russo
4,981,471	A	1/1991	Quinn et al.
4,994,034	A	2/1991	Botich et al.
5,007,900	A	4/1991	Picha et al.
5,071,405	A	12/1991	Piontek et al.
5,073,166	A	12/1991	Parks et al.
5,111,310	A	5/1992	Parker et al.
5,112,310	A	5/1992	Grobe
5,163,949	A	11/1992	Bonutti
5,178,423	A	1/1993	Combeau
5,203,773	A	4/1993	Green
5,218,970	A	6/1993	Turnbull et al.
5,226,876	A	7/1993	Filipi et al.
5,232,451	A	8/1993	Freitas et al.
5,234,454	A	8/1993	Bangs
5,248,302	A	9/1993	Patrick et al.
5,255,670	A	10/1993	Lomholt
5,273,529	A	12/1993	Idowu
5,275,610	A	1/1994	Eberbach
5,279,564	A	1/1994	Taylor
5,308,325	A	5/1994	Quinn et al.
5,309,906	A	5/1994	LaBombard
5,324,262	A	6/1994	Fischell et al.
5,342,321	A	8/1994	Potter
5,344,439	A	9/1994	Otten
5,365,967	A	11/1994	Moore
5,399,173	A	3/1995	Parks et al.
5,403,290	A	4/1995	Noble
5,411,491	A	5/1995	Goldhardt et al.
5,429,598	A	7/1995	Waxman et al.
5,429,605	A	7/1995	Richling et al.
5,439,444	A	8/1995	Andersen et al.
5,458,572	A	10/1995	Campbell et al.
5,458,583	A	10/1995	McNeely et al.
5,462,528	A	10/1995	Roewer
5,462,561	A	10/1995	Voda
5,470,314	A	11/1995	Walinsky
5,514,112	A	5/1996	Chu et al.
5,522,961	A	6/1996	Leonhardt
5,527,280	A	6/1996	Goelz
5,549,657	A	8/1996	Stern et al.
D373,418	S	9/1996	Szpak
5,556,385	A	9/1996	Andersen
5,681,280	A	10/1997	Rusk et al.
5,720,734	A	2/1998	Copenhaver et al.
5,749,852	A	5/1998	Schwab et al.
5,792,119	A	8/1998	Marx
5,836,924	A	11/1998	Kelliher et al.
5,840,065	A	11/1998	Goldhardt et al.
5,860,960	A	1/1999	Quinn
5,910,128	A	6/1999	Quinn
5,935,107	A	8/1999	Taylor et al.
5,941,855	A	8/1999	Picha et al.
5,993,473	A	11/1999	Chan et al.
5,997,503	A	12/1999	Willis et al.
5,997,546	A	12/1999	Foster et al.
6,033,379	A	3/2000	Barra et al.
6,045,536	A	4/2000	Meier et al.
6,050,987	A	4/2000	Rosenbaum
6,066,112	A	5/2000	Quinn
6,066,155	A	5/2000	Amann et al.
6,077,243	A	6/2000	Quinn
6,113,572	A	9/2000	Gailey et al.
6,113,579	A	9/2000	Eidenschink et al.
6,149,575	A	11/2000	Leonhardt
6,186,985	B1	2/2001	Snow
6,221,042	B1	4/2001	Adams
6,228,063	B1	5/2001	Aboul-Hosn
6,264,631	B1	7/2001	Willis et al.
6,315,789	B1	11/2001	Cragg
6,319,244	B2	11/2001	Suresh et al.
6,432,080	B2	8/2002	Pederson, Jr. et al.
6,506,179	B1	1/2003	Tiefenthal et al.
6,530,898	B1	3/2003	Nimkar et al.
6,565,536	B1	5/2003	Sohn
6,582,395	B1	6/2003	Burkett et al.
6,595,971	B1	7/2003	von Dyck et al.
6,632,197	B2	10/2003	Lyon
6,641,177	B1	11/2003	Pinciaro
6,666,853	B2	12/2003	Chu et al.
6,669,681	B2	12/2003	Jepson et al.
6,702,336	B1	3/2004	Chelchowski et al.
6,705,320	B1	3/2004	Anderson
6,732,734	B2	5/2004	Ogushi et al.
D490,890	S	6/2004	Li
6,858,019	B2	2/2005	McGuckin, Jr. et al.
6,878,130	B2	4/2005	Fournie et al.
6,896,665	B2	5/2005	Picha et al.
6,916,307	B2	7/2005	Willis et al.
6,929,621	B2	8/2005	Whitmore et al.
6,960,222	B2	11/2005	Vo et al.
6,976,980	B2	12/2005	Brenner et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,997,909	B2	2/2006	Goldberg
7,008,438	B2	3/2006	O'Brien
7,008,441	B2	3/2006	Zucker
7,041,083	B2	5/2006	Chu et al.
7,060,050	B2	6/2006	Kliem et al.
7,070,587	B2	7/2006	Meier
7,124,489	B2	10/2006	Triebes et al.
7,186,238	B2	3/2007	Elbert et al.
7,220,243	B2	5/2007	Bonnette et al.
7,341,284	B2	3/2008	Mittersteiner et al.
7,534,224	B2	5/2009	Triebes et al.
7,547,303	B2	6/2009	DeLegge
7,582,072	B2	9/2009	McMichael
7,621,903	B2	11/2009	DeLegge
7,625,361	B2	12/2009	Suzuki et al.
7,628,775	B2	12/2009	Adams et al.
7,819,840	B2	10/2010	Burnside et al.
8,206,347	B2	6/2012	Burnside et al.
8,226,632	B2	7/2012	Zawacki et al.
8,715,244	B2	5/2014	Prechtel et al.
8,858,533	B2	10/2014	Downing et al.
9,572,751	B2	2/2017	Prechtel et al.
2002/0093199	A1	7/2002	Le
2003/0055454	A1	3/2003	Zucker
2003/0088213	A1	5/2003	Schweikert et al.
2003/0120260	A1	6/2003	Chu et al.
2003/0212385	A1	11/2003	Brenner et al.
2003/0225376	A1	12/2003	Fournie et al.
2004/0041399	A1	3/2004	Chelchowski et al.
2004/0087984	A1	5/2004	Kupiecki et al.
2004/0103518	A1	6/2004	Triebes et al.
2004/0106899	A1	6/2004	McMichael et al.
2004/0106900	A1	6/2004	Triebes et al.
2004/0106901	A1	6/2004	Letson et al.
2004/0147874	A1	7/2004	Kliem et al.
2004/0181235	A1	9/2004	Daignault et al.
2005/0038381	A1	2/2005	McMichael
2005/0200122	A1	9/2005	Mittersteiner et al.
2005/0267415	A1	12/2005	Jacques
2006/0206095	A1	9/2006	Chu et al.
2006/0270989	A1	11/2006	McMichael et al.
2006/0276746	A1	12/2006	Burnside et al.
2007/0021771	A1	1/2007	Oepen et al.
2007/0088259	A1	4/2007	Chu et al.
2007/0123842	A1	5/2007	Teague et al.
2007/0244426	A1	10/2007	Hart et al.
2007/0255209	A1	11/2007	Crooms et al.
2007/0276356	A1	11/2007	Downing et al.
2008/0058730	A1	3/2008	Melsheimer
2008/0188897	A1	8/2008	Krebs et al.
2009/0112183	A1	4/2009	Jacques
2009/0254114	A1	10/2009	Hirszowicz et al.
2009/0318873	A1	12/2009	Bailey
2010/0004601	A1	1/2010	Deckard
2010/0010448	A1	1/2010	Deckard
2010/0057013	A1	3/2010	Harada
2010/0185155	A1	7/2010	McMichael et al.
2010/0312192	A1	12/2010	Fitzgerald et al.
2011/0009828	A1	1/2011	Prechtel et al.
2011/0152762	A1	6/2011	Hershey et al.
2011/0196341	A1	8/2011	Howell
2012/0053485	A1	3/2012	Bloom
2012/0238959	A1	9/2012	Thorne et al.
2012/0245519	A1	9/2012	Rotella et al.
2014/0243785	A1	8/2014	Prechtel et al.

FOREIGN PATENT DOCUMENTS

EP	2060293	A1	5/2009
EP	2451512	A1	5/2012
GB	2150837	A	7/1985
JP	S60-145154	A	7/1985
JP	H05-115429	A	5/1993
JP	H08-506249	A	7/1996
JP	2000-515797	T	11/2000
JP	2006-035001	A	2/2006
JP	2006-296794	A	11/2006
JP	2009-089927	A	4/2009
JP	2009-534111	A	9/2009
JP	4988725	B2	8/2012
JP	2012192182	A	10/2012
JP	5184512		4/2013
JP	2013-518697	A	5/2013
WO	9819730	A1	5/1998
WO	9852631	A1	11/1998
WO	02087492	A1	11/2002
WO	2004050009	A1	6/2004
WO	2006-111416	A1	10/2006
WO	2007087254	A2	8/2007
WO	2007-124167	A2	11/2007
WO	2009135141	A1	11/2009
WO	2011005847	A1	1/2011
WO	2011100310	A2	8/2011

OTHER PUBLICATIONS

U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Non-Final Office Action dated Sep. 24, 2015.
U.S. Appl. No. 14/270,199, filed May 5, 2014 Non-Final Office Action dated Jan. 4, 2016.
U.S. Appl. No. 13/024,046, filed Feb. 9, 2011 Non-Final Office Action dated Nov. 29, 2013.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Advisory Action dated Jul. 16, 2014.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Final Office Action dated Feb. 13, 2014.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Final Office Action dated May 5, 2014.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Non-Final Office Action dated Sep. 3, 2013.
EP 11742731.0 filed Sep. 4, 2012 extended European Search Report dated Aug. 6, 2013.
JP 2007-519438 filed Jun. 29, 2005 Decision to Grant dated Sep. 4, 2012.
JP 2007-519438 filed Jun. 29, 2005 Office Action dated Nov. 30, 2010.
Michaud, Laurent et al, Longevity of Balloon-Stabilized Skin-Level Gastrostomy Device, Journal of Pediatric Gastroenterology and Nutrition, 38: 426-429; Apr. 2004.
PCT/US11/24176 filed Feb. 9, 2011 International Preliminary Report on Patentability dated Oct. 11, 2012.
PCT/US11/24176 filed Feb. 9, 2011 International Search Report and Written Opinion dated Jul. 8, 2011.
PCT/US2005/023297 filed Jun. 29, 2005 International Preliminary Report on Patentability dated Jan. 9, 2007.
PCT/US2005/023297 filed Jun. 29, 2005 Search Report dated May 26, 2006.
PCT/US2005/023297 filed Jun. 29, 2005 Written Opinion dated May 26, 2006.
PCT/US2006/022020 filed Jun. 6, 2006 International Preliminary Report on Patentability dated Dec. 6, 2007.
PCT/US2006/022020 filed Jun. 6, 2006 Search Report dated Jan. 25, 2007.
PCT/US2006/022020 filed Jun. 6, 2006 Written Opinion dated Jan. 25, 2007.
PCT/US2010/041192 filed Jul. 7, 2010 International Search Report dated Sep. 20, 2010.
PCT/US2010/041192 filed Jul. 7, 2010 Written Opinion dated Sep. 20, 2010.
U.S. Appl. No. 11/127,662, filed May 12, 2005 Advisory Action dated May 16, 2008.
U.S. Appl. No. 11/127,662, filed May 12, 2005 Final Office Action dated Mar. 5, 2008.
U.S. Appl. No. 11/127,662, filed May 12, 2005 Final Office Action dated Mar. 6, 2007.
U.S. Appl. No. 11/127,662, filed May 12, 2005 Non-Final Office Action dated Aug. 9, 2007.
U.S. Appl. No. 11/127,662, filed May 12, 2005 Non-Final Office Action dated Jul. 9, 2008.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 11/127,662, filed May 12, 2005 Non-Final Office Action dated Oct. 17, 2006.
U.S. Appl. No. 11/422,559, filed Jun. 6, 2006 Final Office Action dated Apr. 2, 2009.
U.S. Appl. No. 11/422,559, filed Jun. 6, 2006 Non-Final Office Action dated Aug. 8, 2008.
U.S. Appl. No. 11/422,559, filed Jun. 6, 2006 Non-Final Office Action dated Jan. 6, 2010.
U.S. Appl. No. 11/422,559, filed Jun. 6, 2006 Notice of Allowance dated Jun. 24, 2010.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Non-Final Office Action dated Aug. 26, 2008.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Final Office Action dated Jan. 4, 2011.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Final Office Action dated May 4, 2010.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Non-Final Office Action dated Feb. 28, 2014.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Non-Final Office Action dated Jul. 22, 2010.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Non-Final Office Action dated Oct. 2, 2009.
U.S. Appl. No. 11/629,724, filed Jun. 29, 2005 Notice of Allowance dated Jun. 23, 2014.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Final Office Action dated Jan. 13, 2012.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Notice of Allowance dated Jun. 17, 2013.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Advisory Action dated Jun. 18, 2009.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Final Office Action dated Apr. 16, 2009.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Final Office Action dated Jan. 25, 2010.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Non-Final Office Action dated Nov. 24, 2008.
U.S. Appl. No. 11/738,979, filed Apr. 23, 2007 Non-Final Office Action dated Oct. 9, 2009.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Advisory Action dated Apr. 3, 2012.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Final Office Action dated Jan. 13, 2012.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Final Office Action dated Jun. 26, 2013.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Non-Final Office Action dated Dec. 18, 2012.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Non-Final Office Action dated Jul. 29, 2011.
U.S. Appl. No. 12/831,644, filed Jul. 7, 2010 Final Office Action dated Nov. 7, 2012.
U.S. Appl. No. 12/831,644, filed Jul. 7, 2010 Non-Final Office Action dated Aug. 1, 2013.
U.S. Appl. No. 12/831,644, filed Jul. 7, 2010 Non-Final Office Action dated Mar. 30, 2012.
U.S. Appl. No. 12/831,644, filed Jul. 7, 2010 Notice of Allowance dated Dec. 26, 2013.
U.S. Appl. No. 12/902,987, filed Oct. 12, 2010 Final Office Action and Reasons for Allowance dated Dec. 22, 2011.
U.S. Appl. No. 12/902,987, filed Oct. 12, 2010 Notice of Allowance dated Dec. 22, 2011.
U.S. Appl. No. 13/024,046, filed Feb. 9, 2011 Final Office Action dated Jun. 26, 2014.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Final Office Action dated May 27, 2015.
U.S. Appl. No. 12/265,102, filed Nov. 5, 2008 Non-Final Office Action dated Dec. 9, 2014.
U.S. Appl. No. 13/024,046, filed Feb. 9, 2011 Final Office Action dated May 4, 2015.
U.S. Appl. No. 13/024,046, filed Feb. 9, 2011 Non-Final Office Action dated Dec. 9, 2014.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Non-Final Office Action dated Jan. 2, 2015.
MX/a/2012/009112 filed Aug. 6, 2012, Unity Objection dated May 18, 2016.
U.S. Appl. No. 13/419,185, filed Mar. 13, 2012 Final Office Action dated Apr. 26, 2016.
U.S. Appl. No. 14/270,199, filed May 5, 2014 Final Office Action dated Jul. 14, 2016.
U.S. Appl. No. 14/270,199, filed May 5, 2014 Notice of Allowance dated Oct. 4, 2016.
JP 2012-057330 filed Mar. 14, 2012 Office Action dated Dec. 20, 2016.

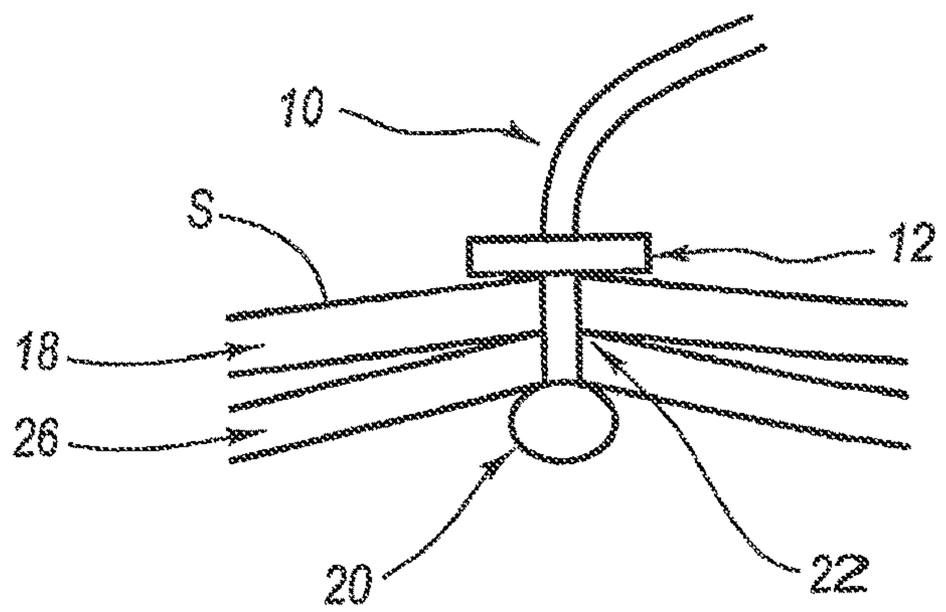


FIG. 1

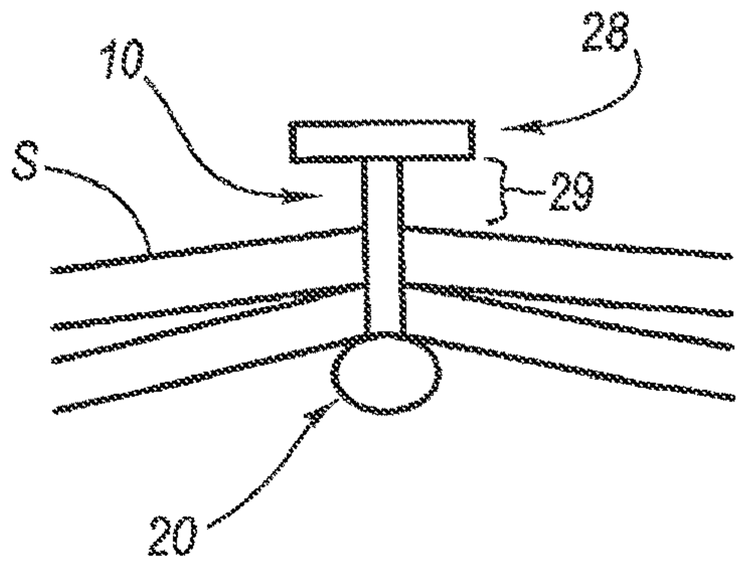


FIG. 2

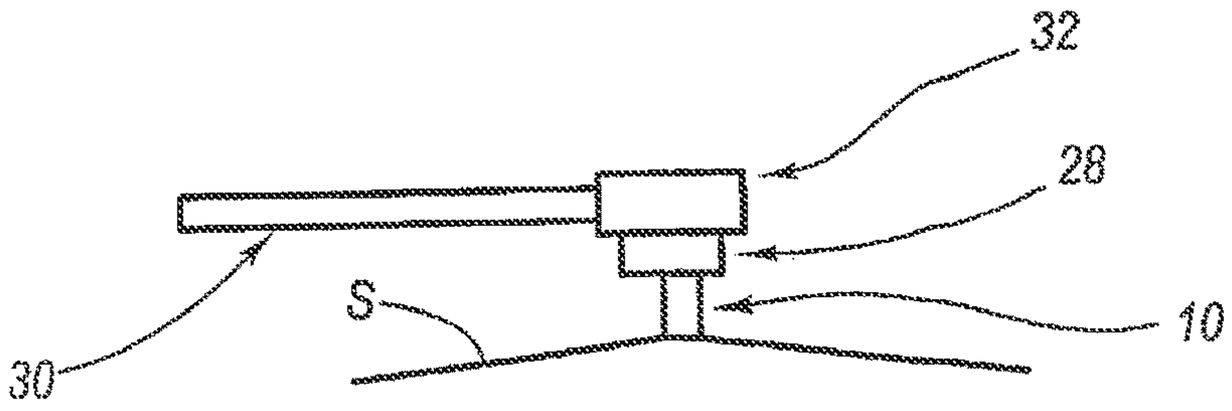


FIG. 3

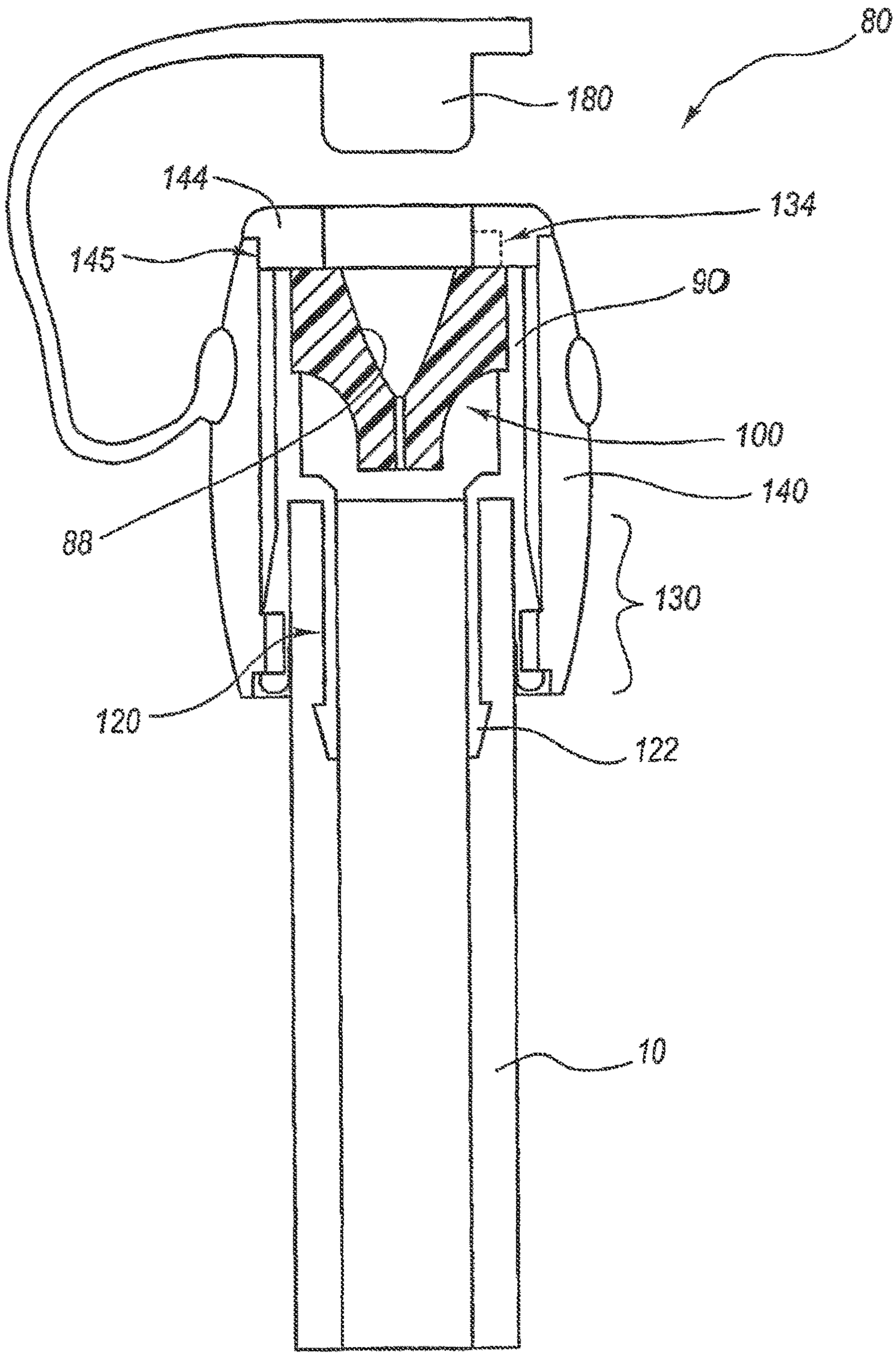


FIG. 4

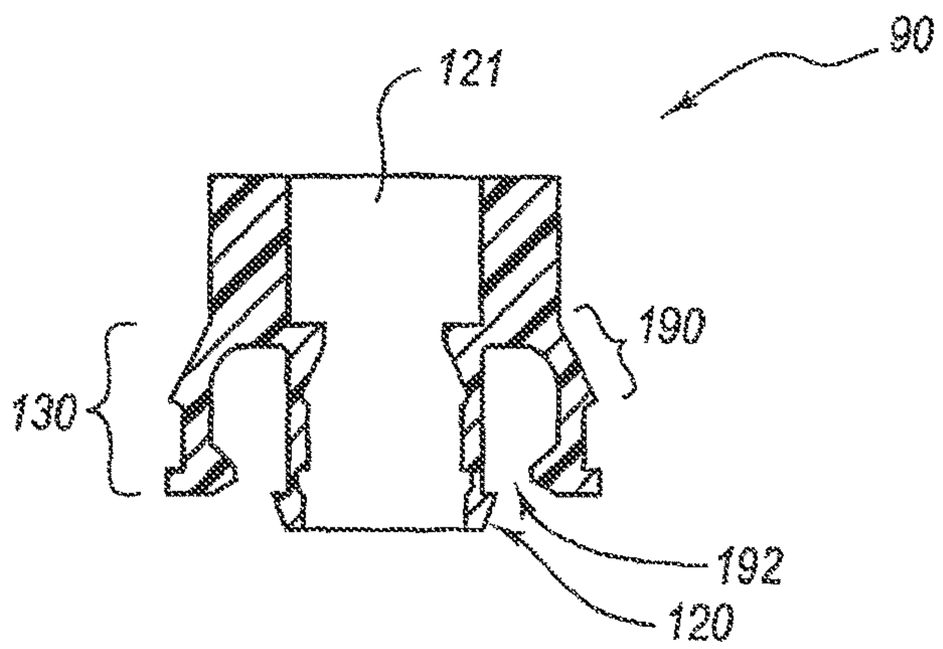


FIG. 5

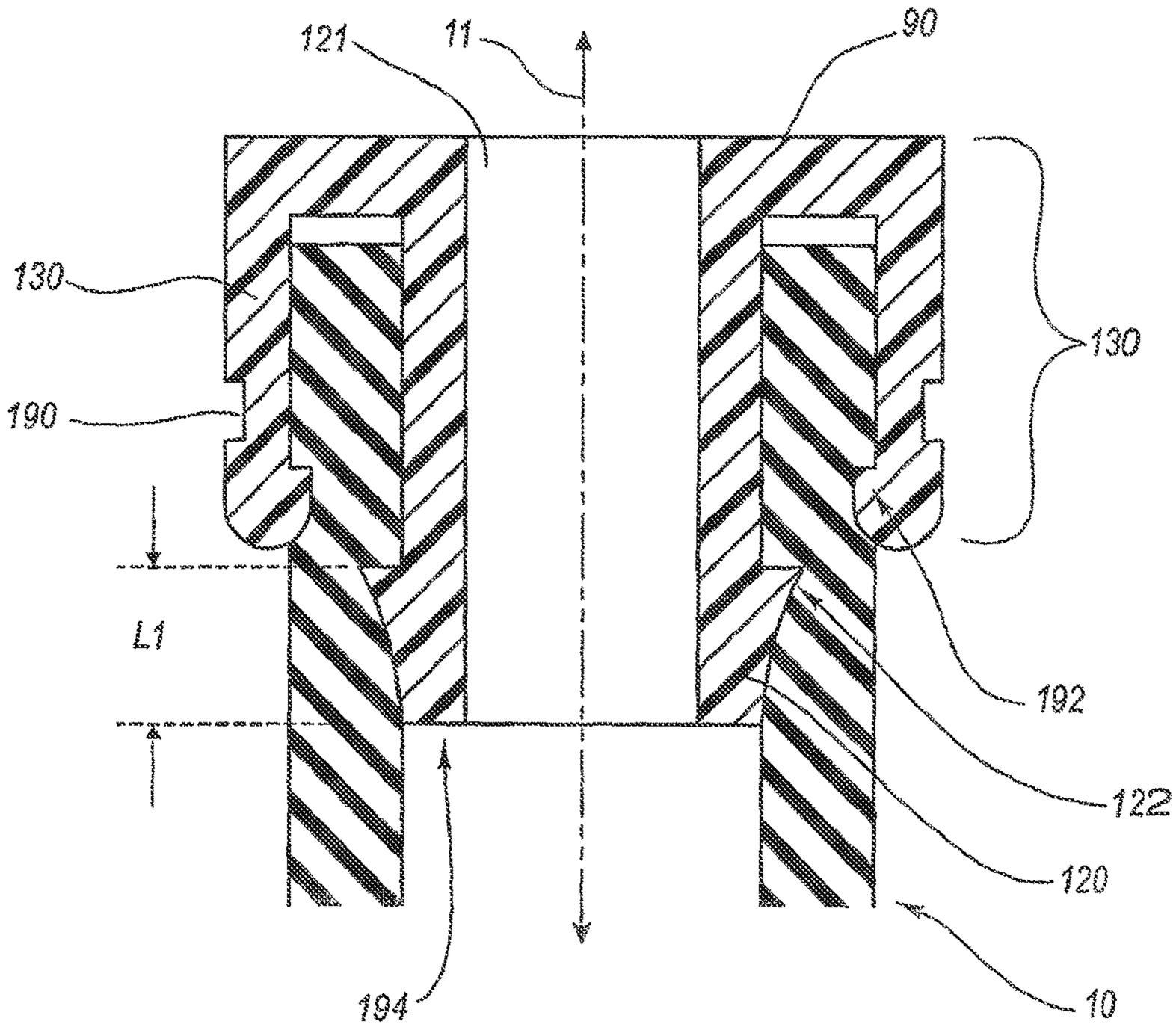


FIG. 6

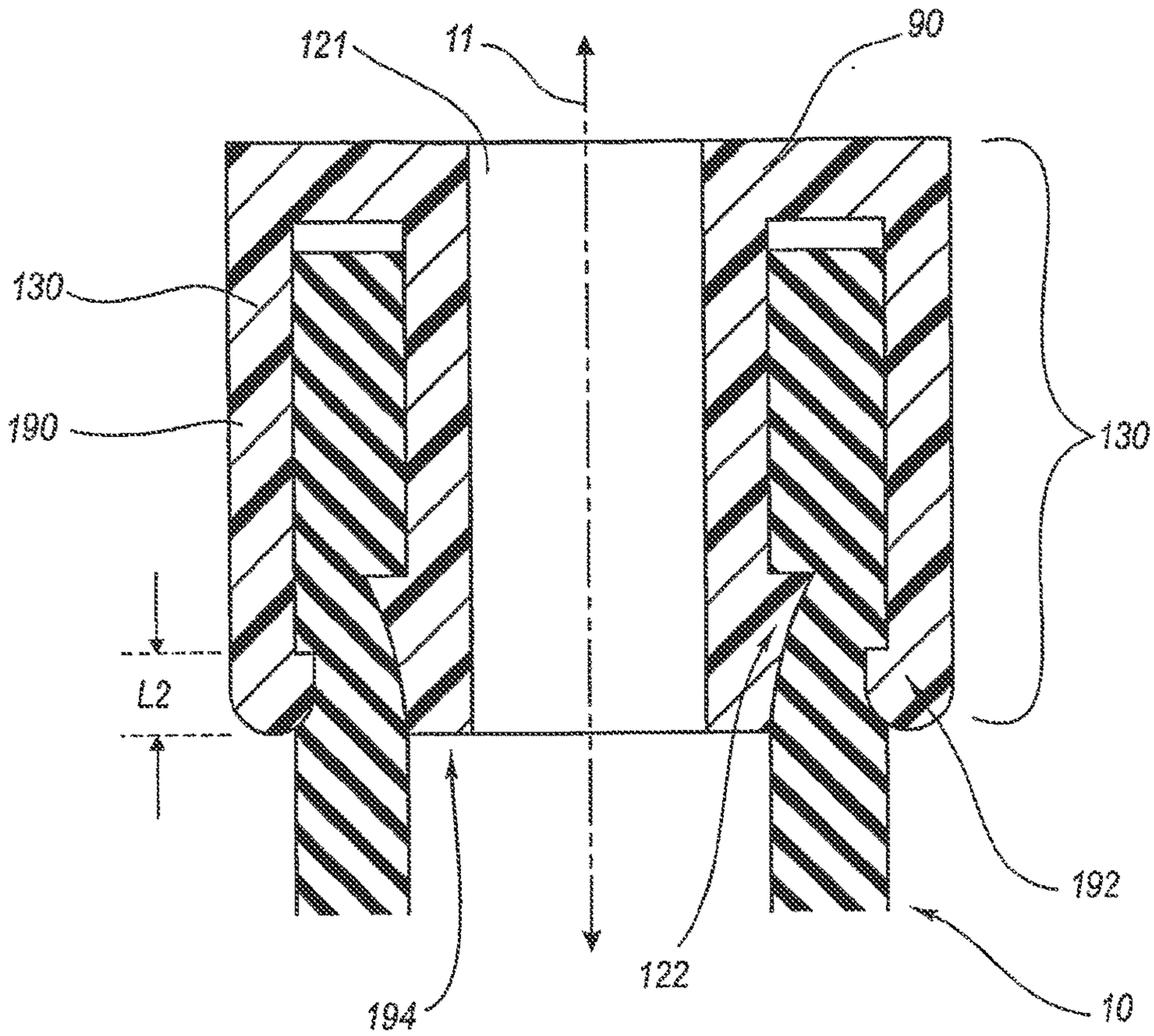


FIG. 7

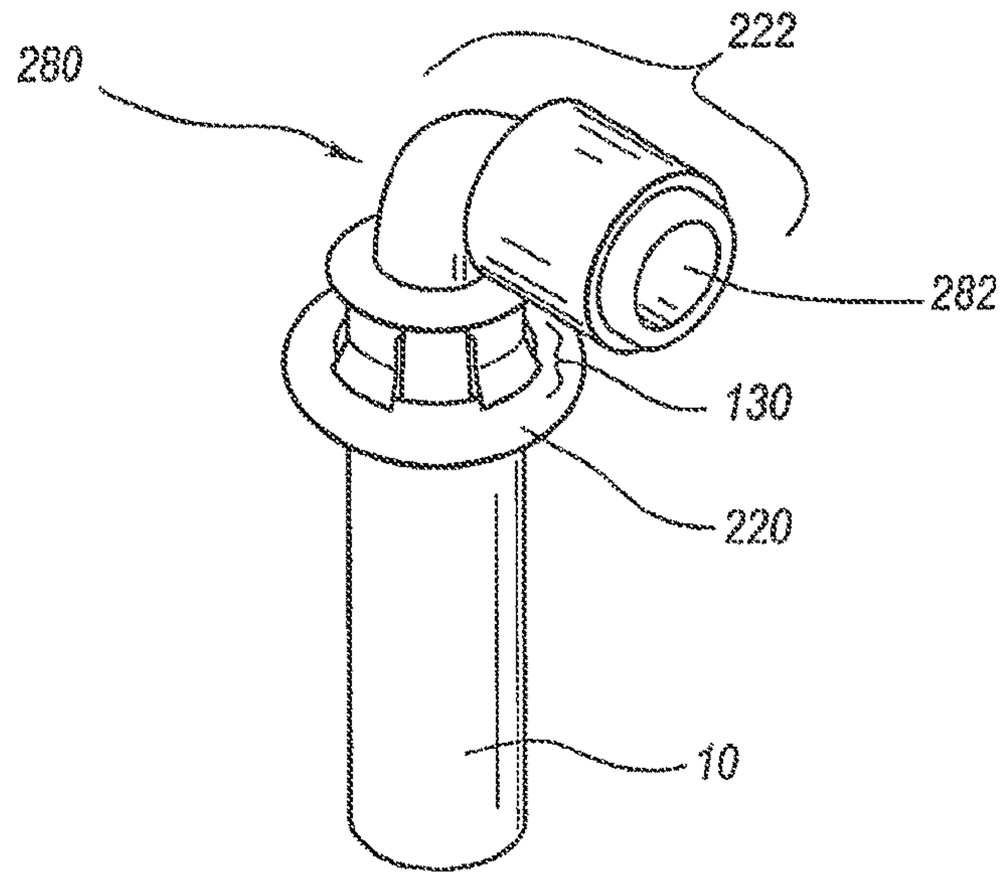


FIG. 8

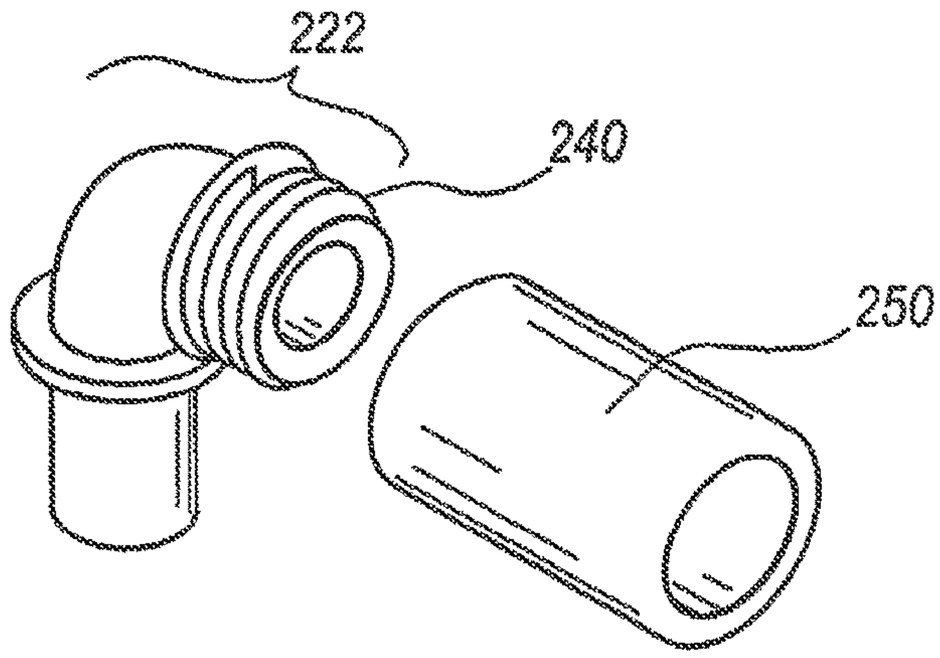


FIG. 9

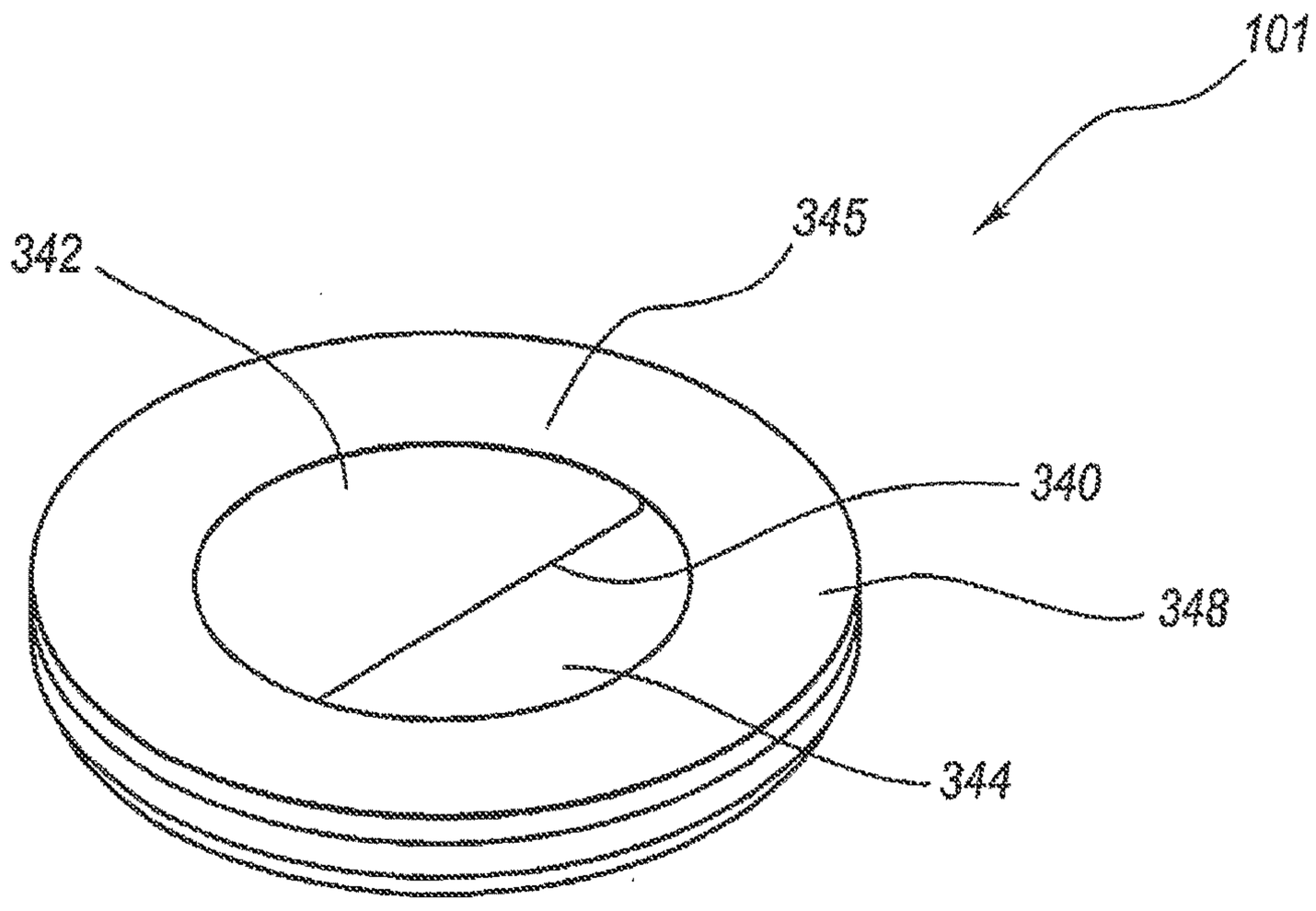


FIG. 10

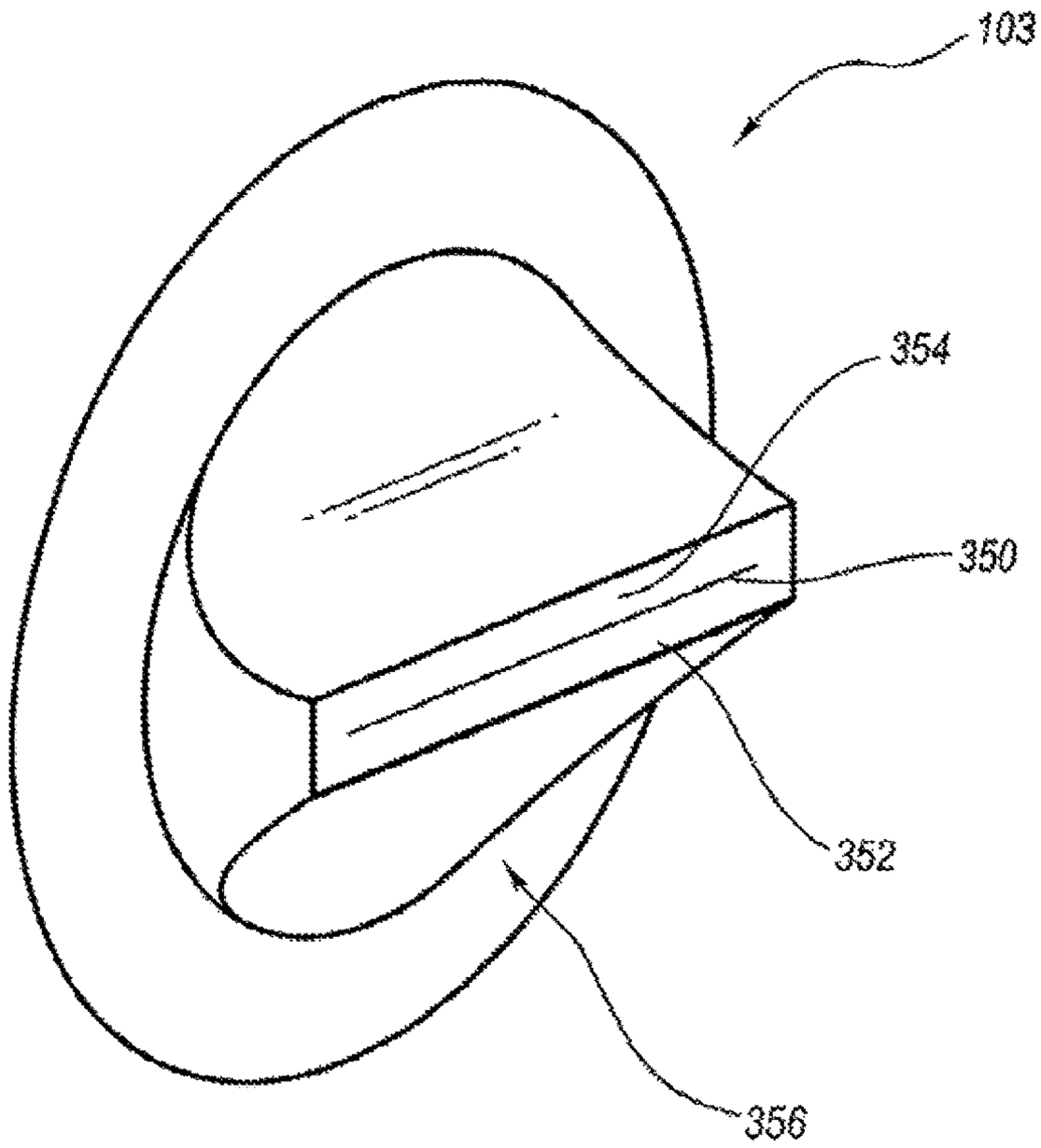


FIG. 11

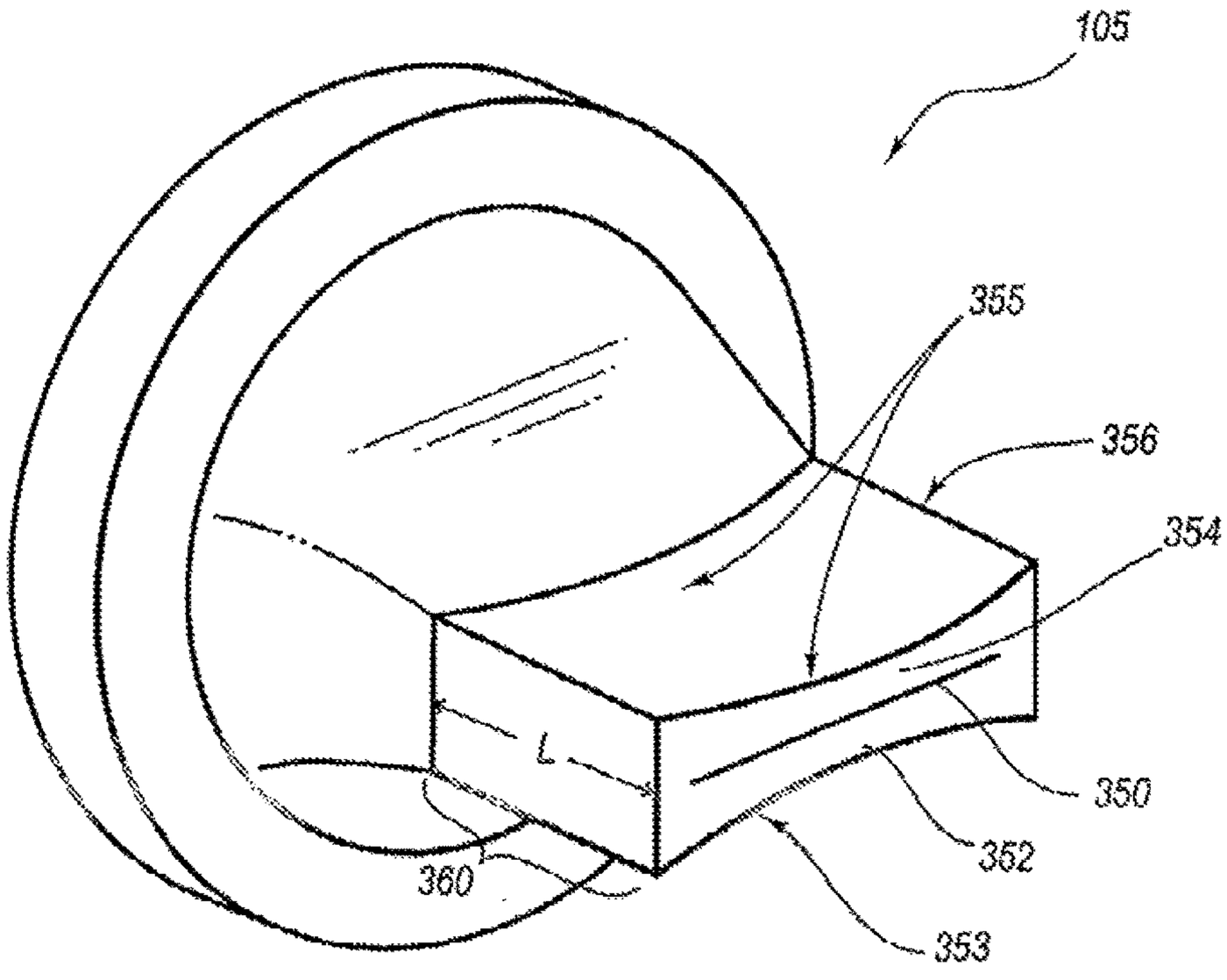


FIG. 12

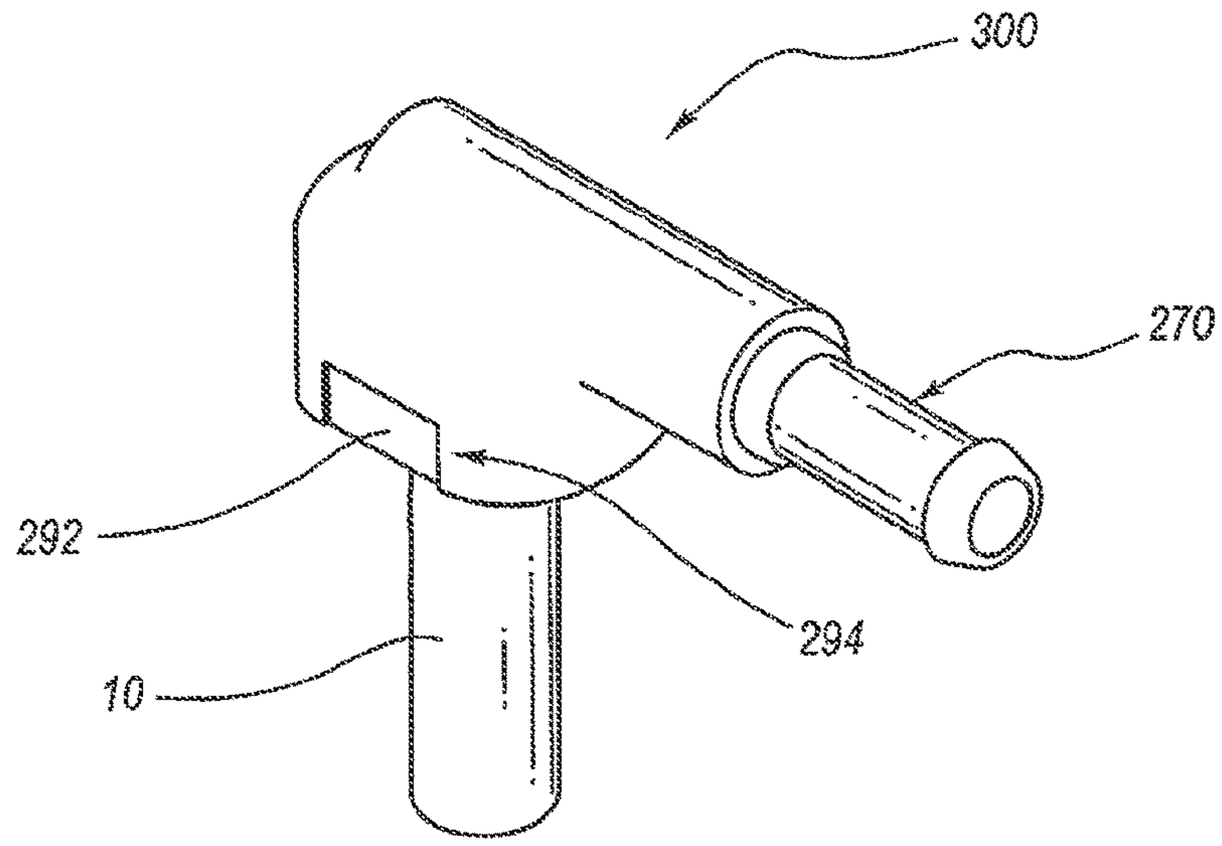


FIG. 13

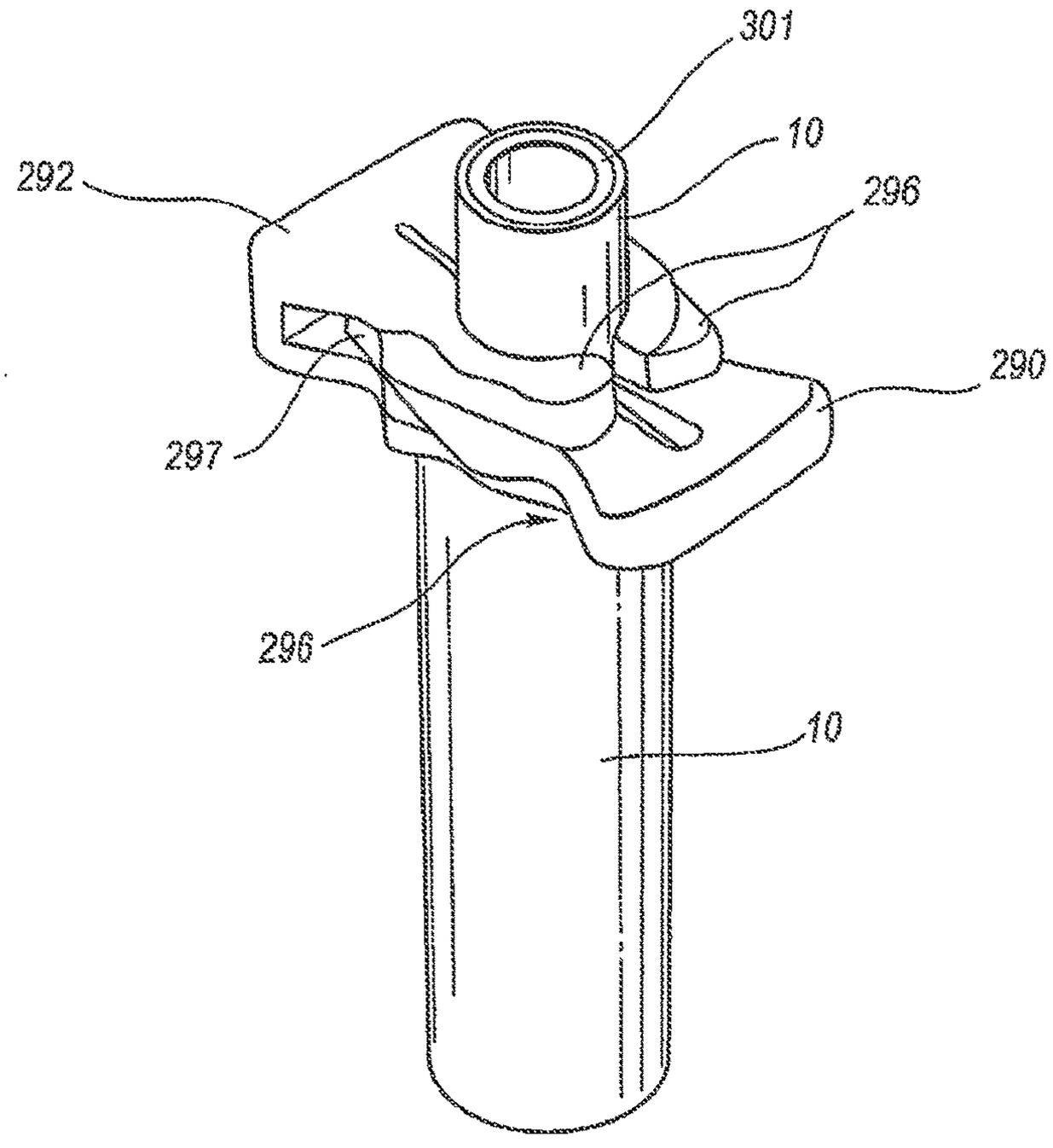


FIG. 14

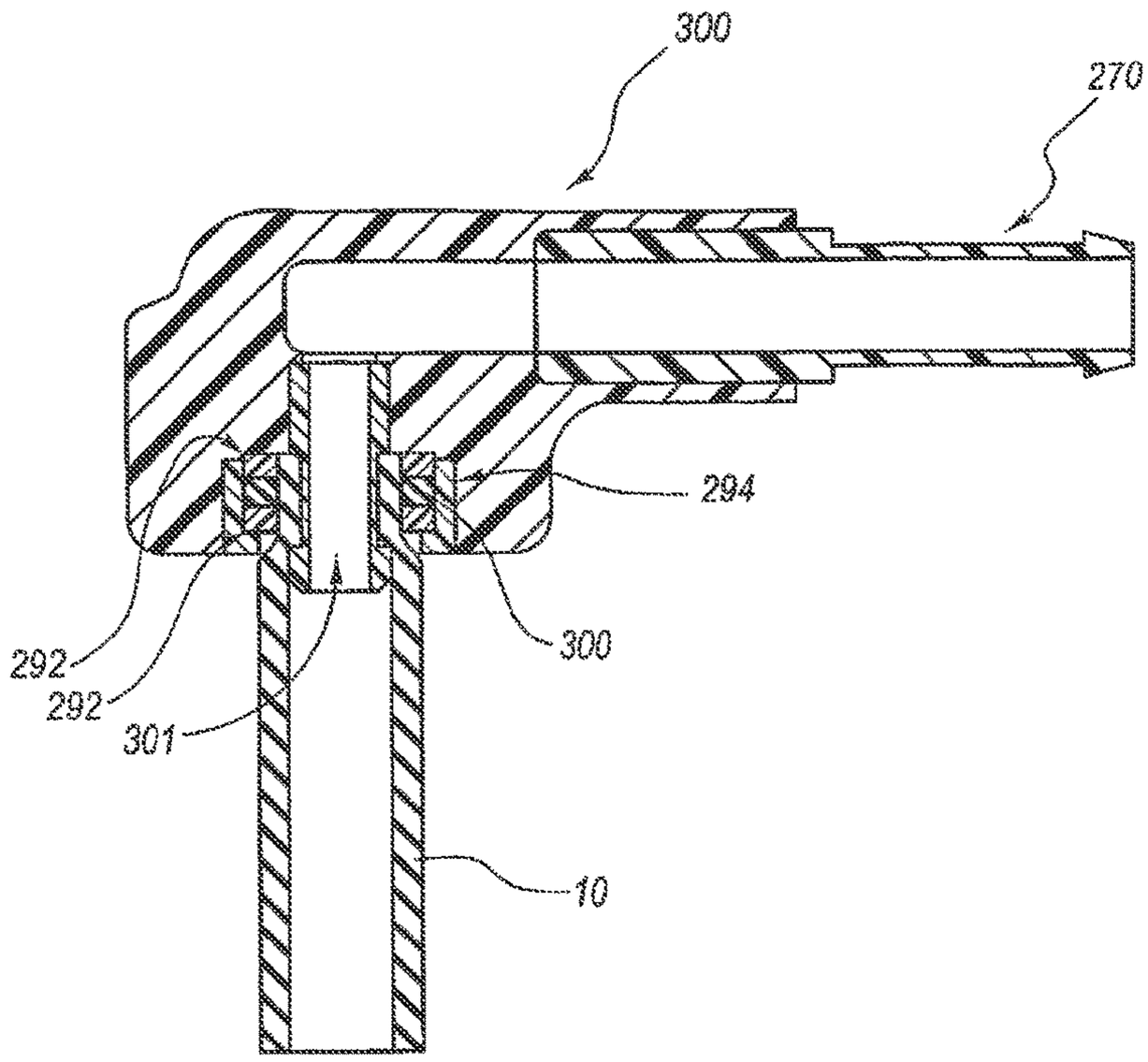


FIG. 15

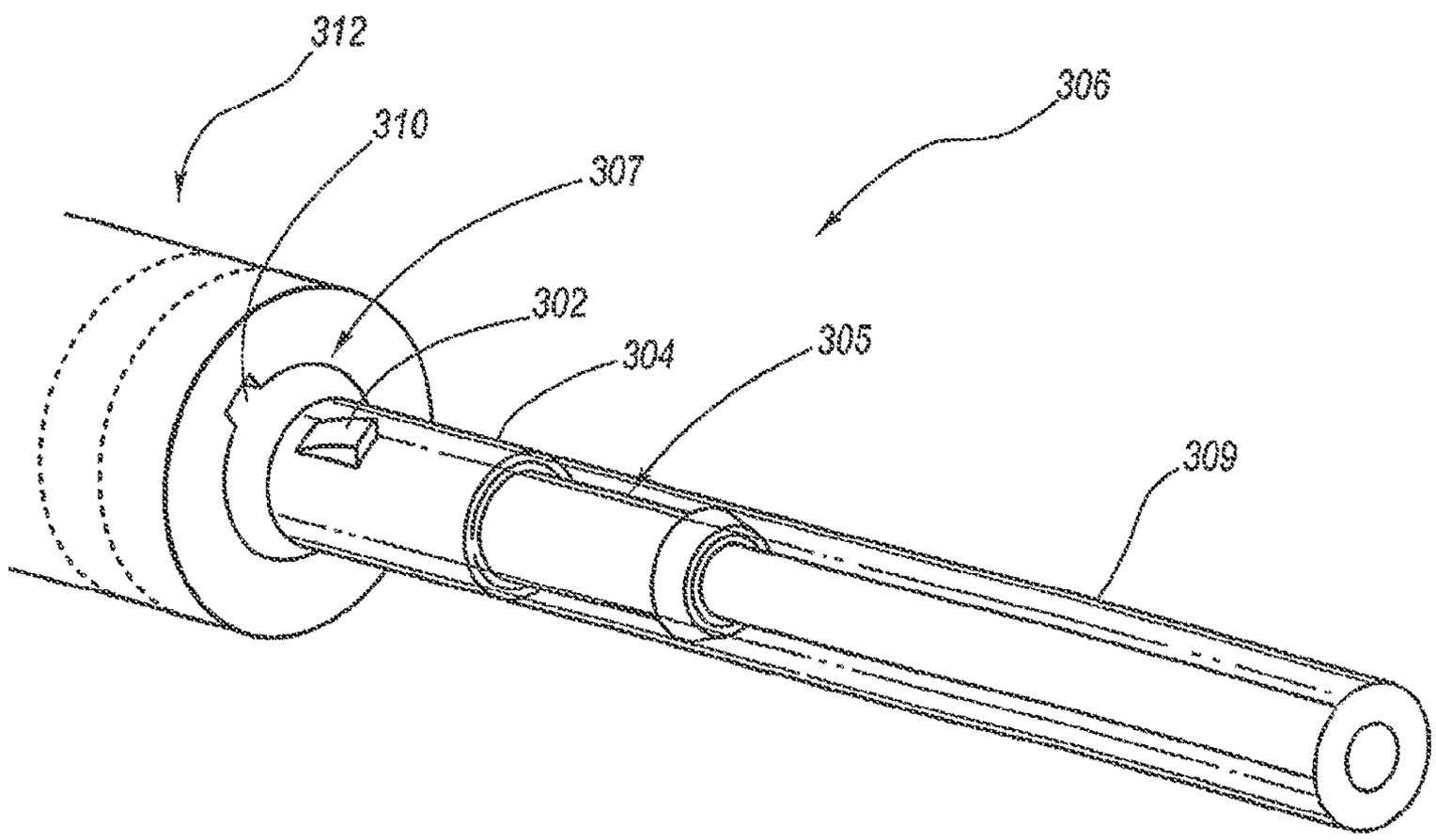


FIG. 16

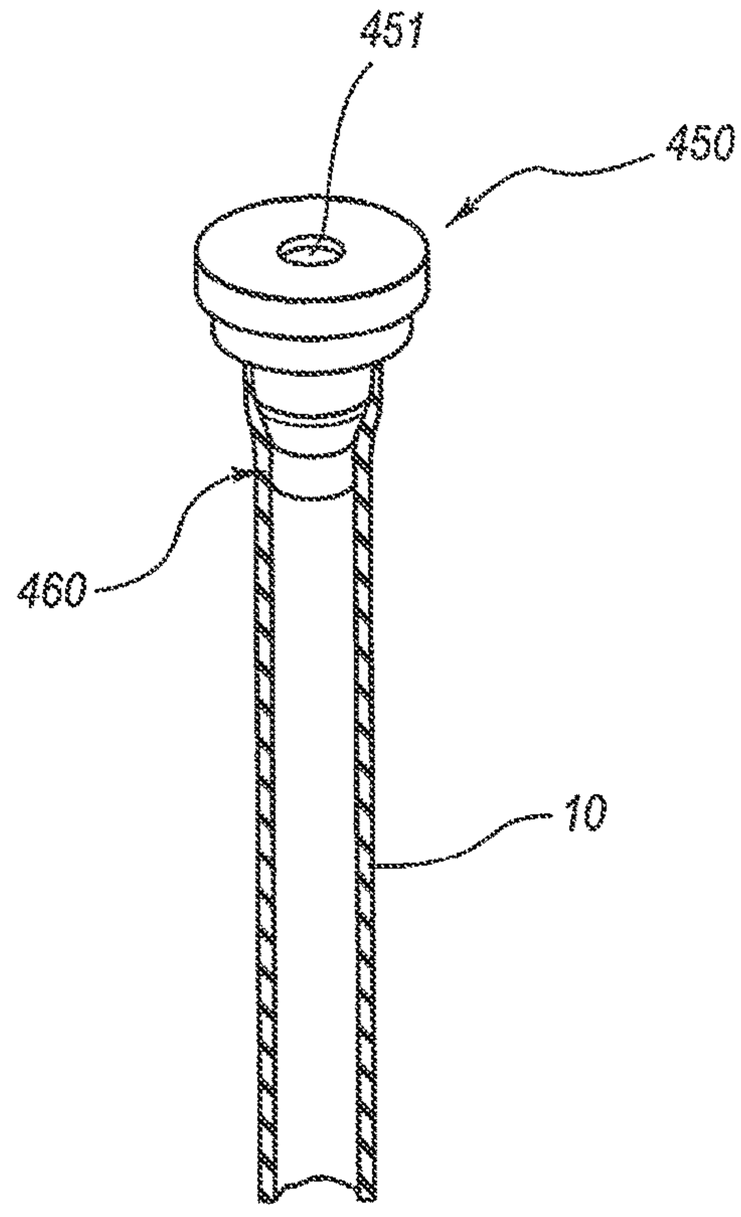


FIG. 17

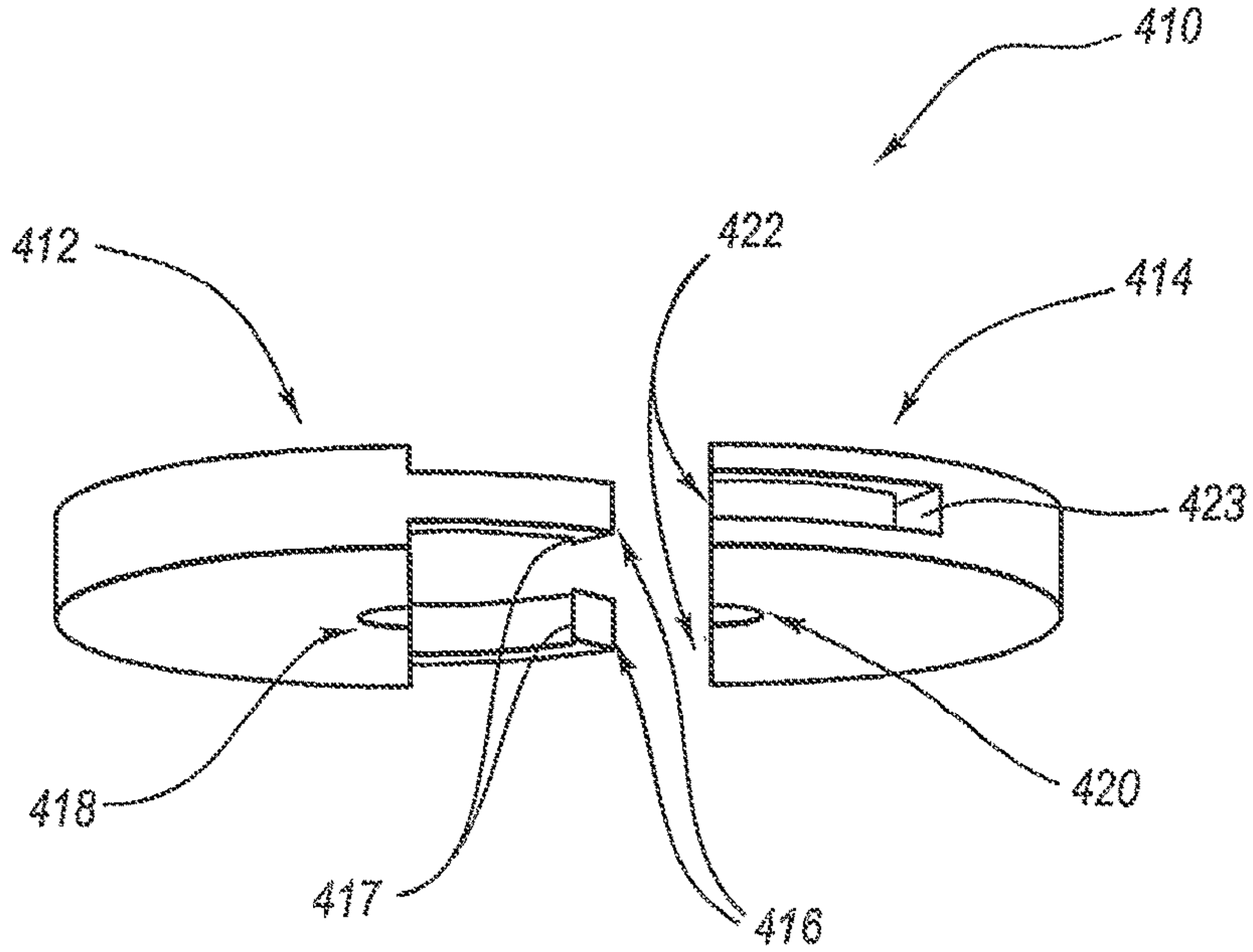


FIG. 18

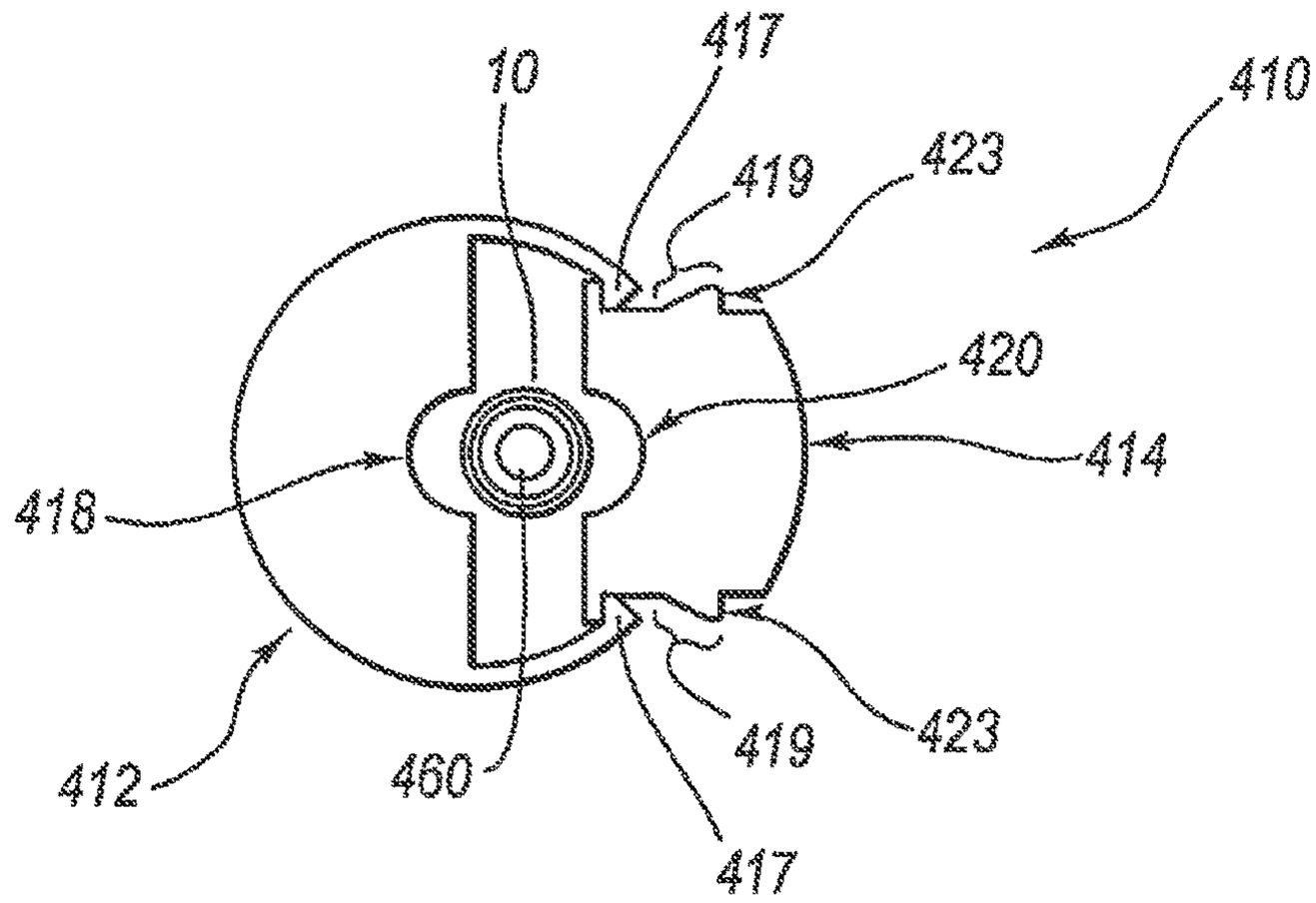

10
417
410
419
423
420
414
418
412
460
419
423
417

FIG. 19

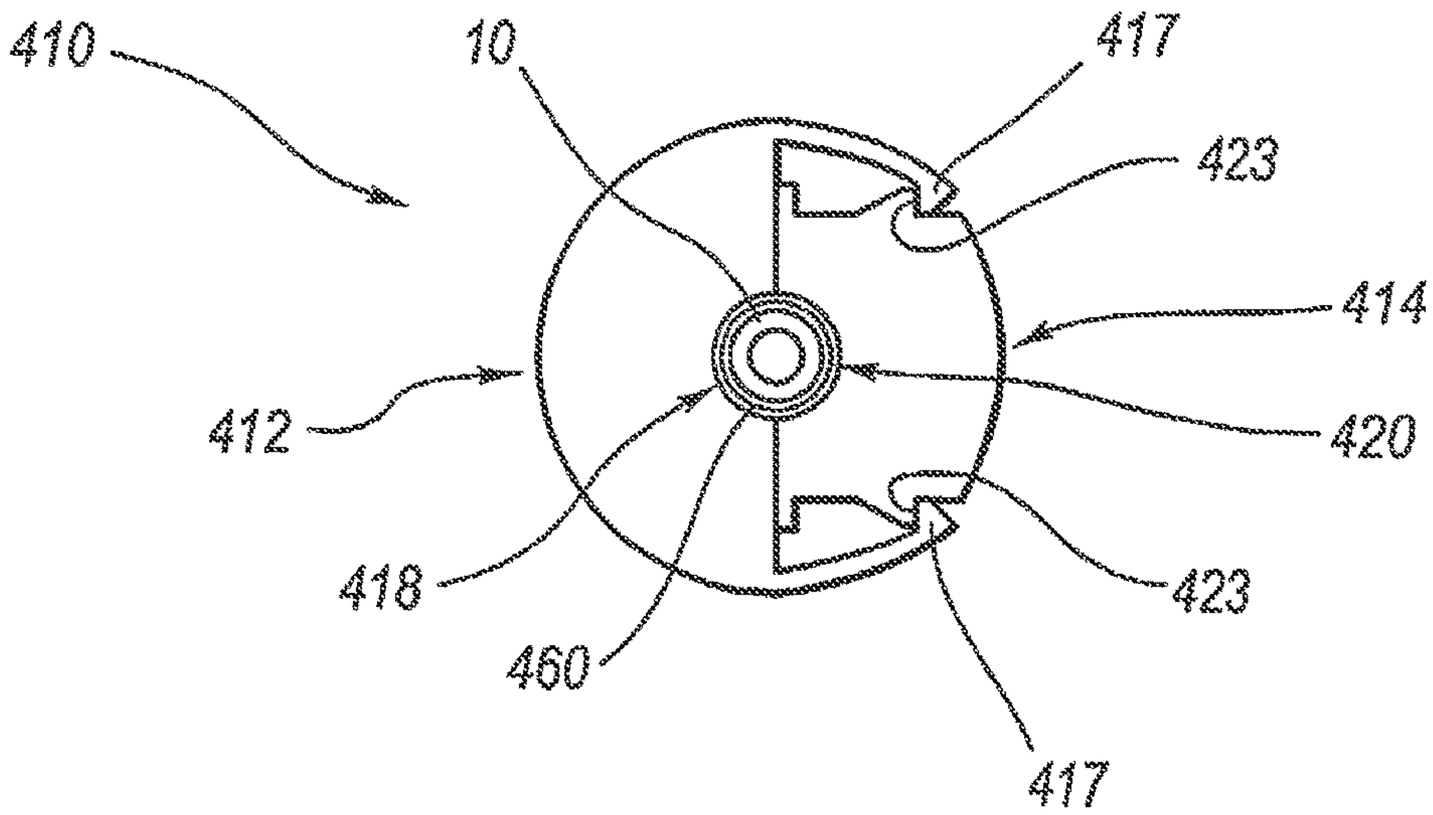

410
10
417
423
414
412
420
418
423
460
417

FIG. 20

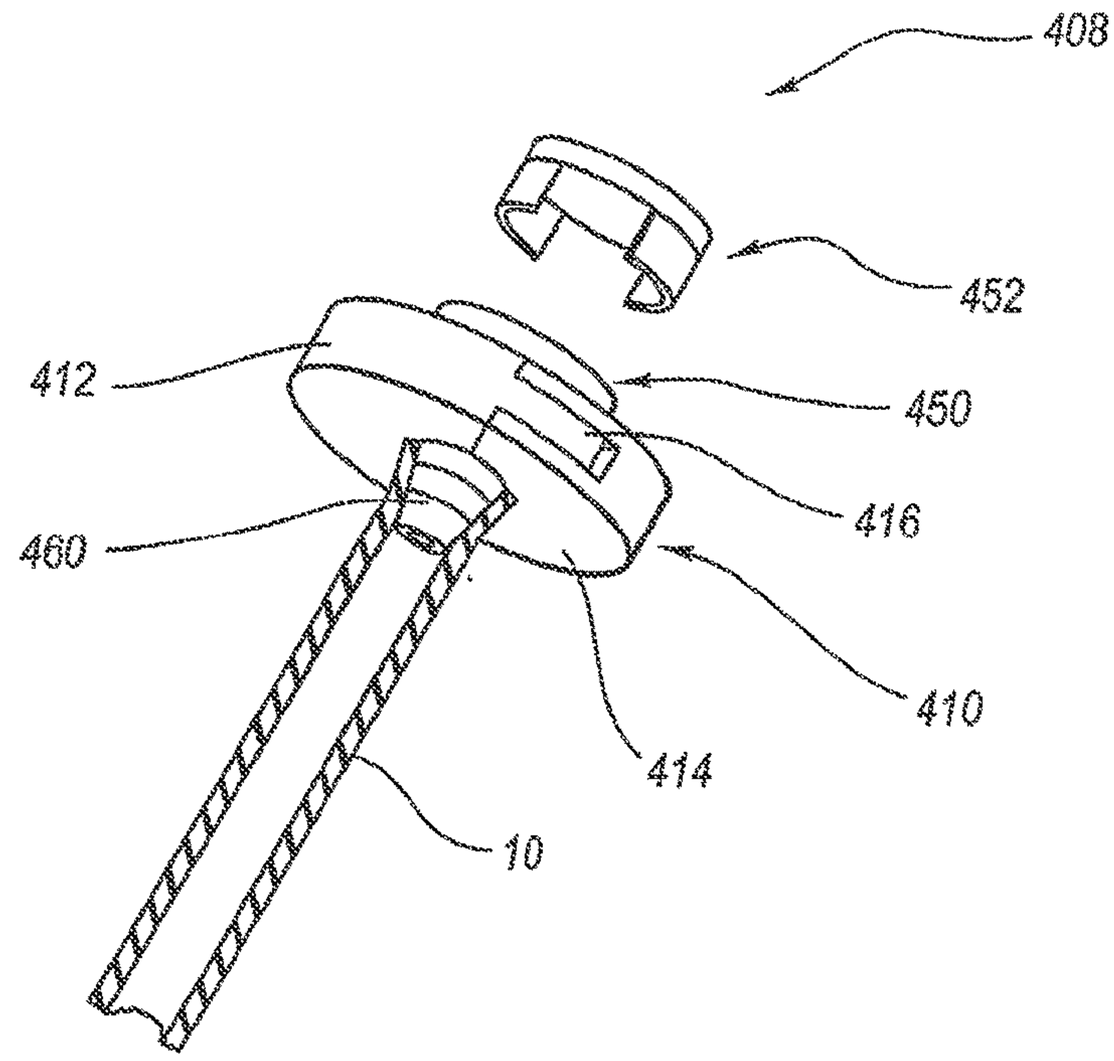

408
452
412
450
460
416
410
414
10

FIG. 21

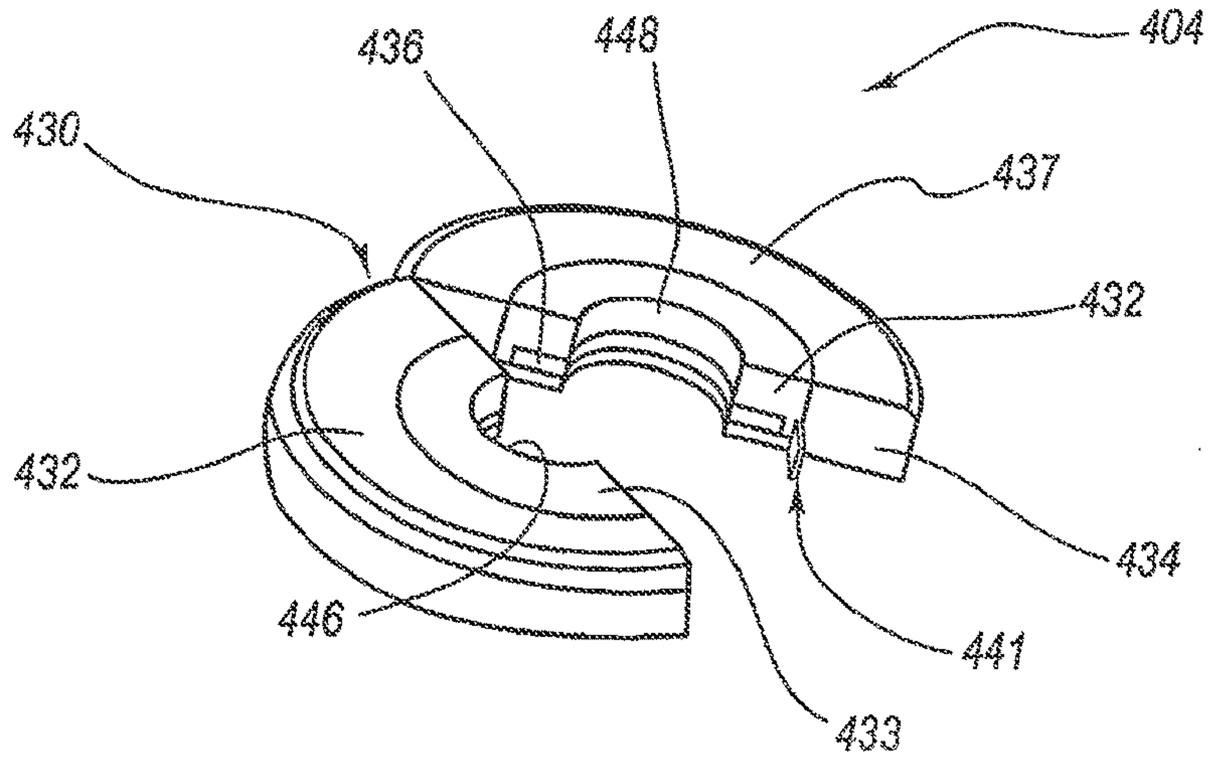

436
448
404
430
437
432
432
434
446
441
433

FIG. 22

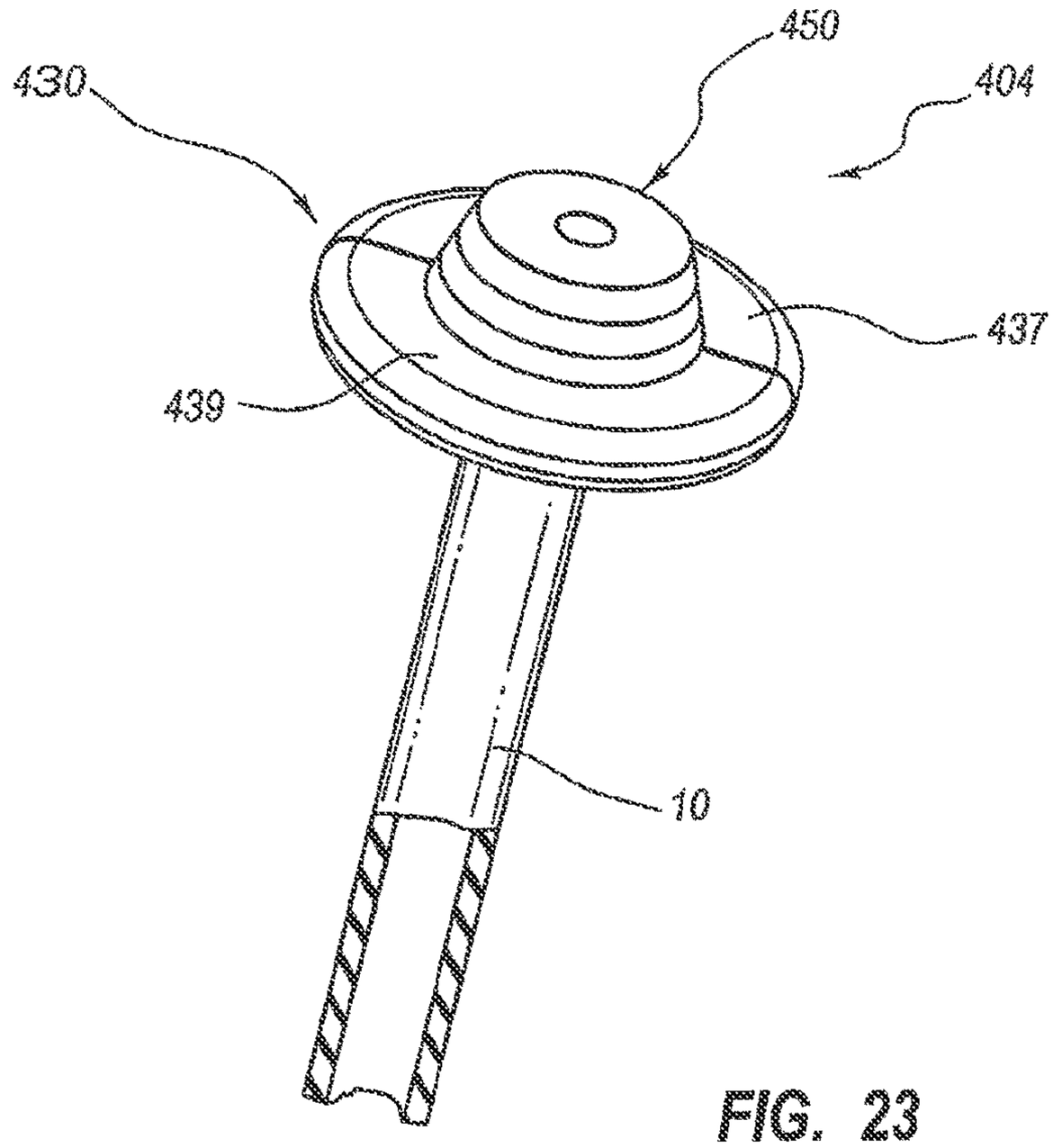


FIG. 23

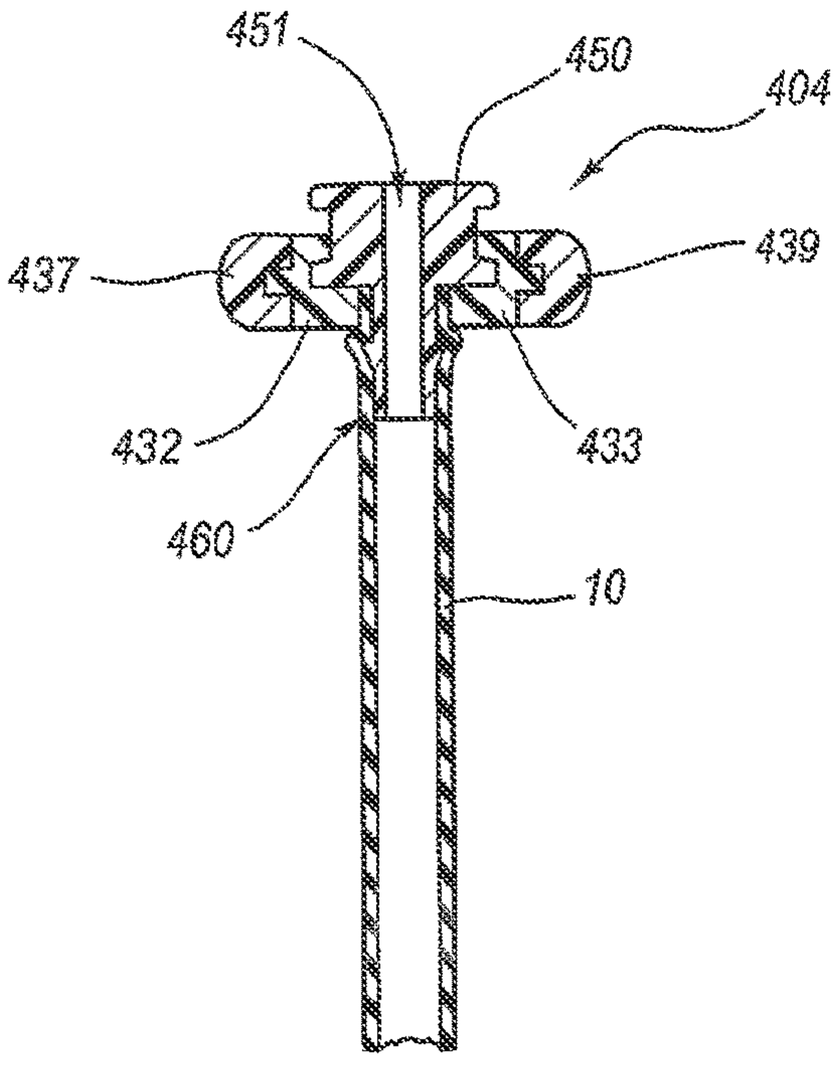


FIG. 24

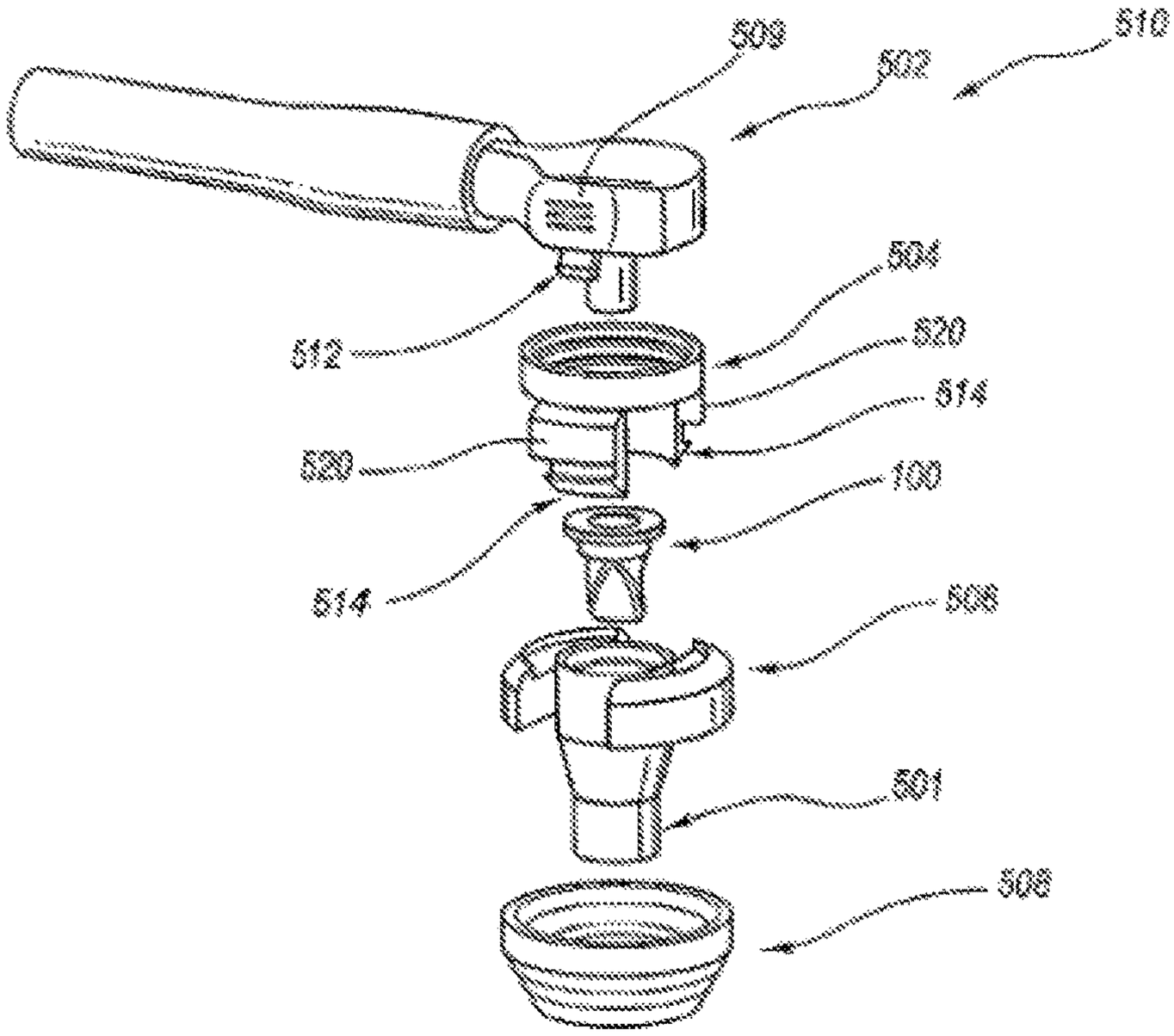

509
502
510
504
512
520
514
520
100
514
508
501
508

FIG. 25

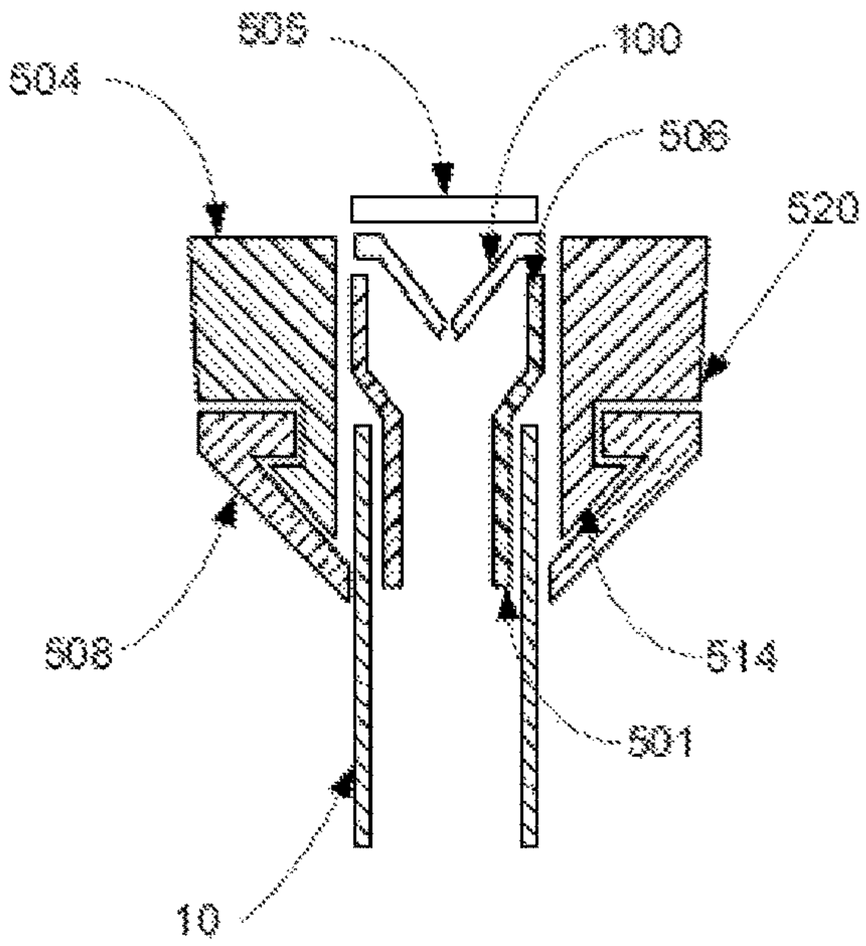

505
100
504
506
520
508
514
501
10

FIG. 26

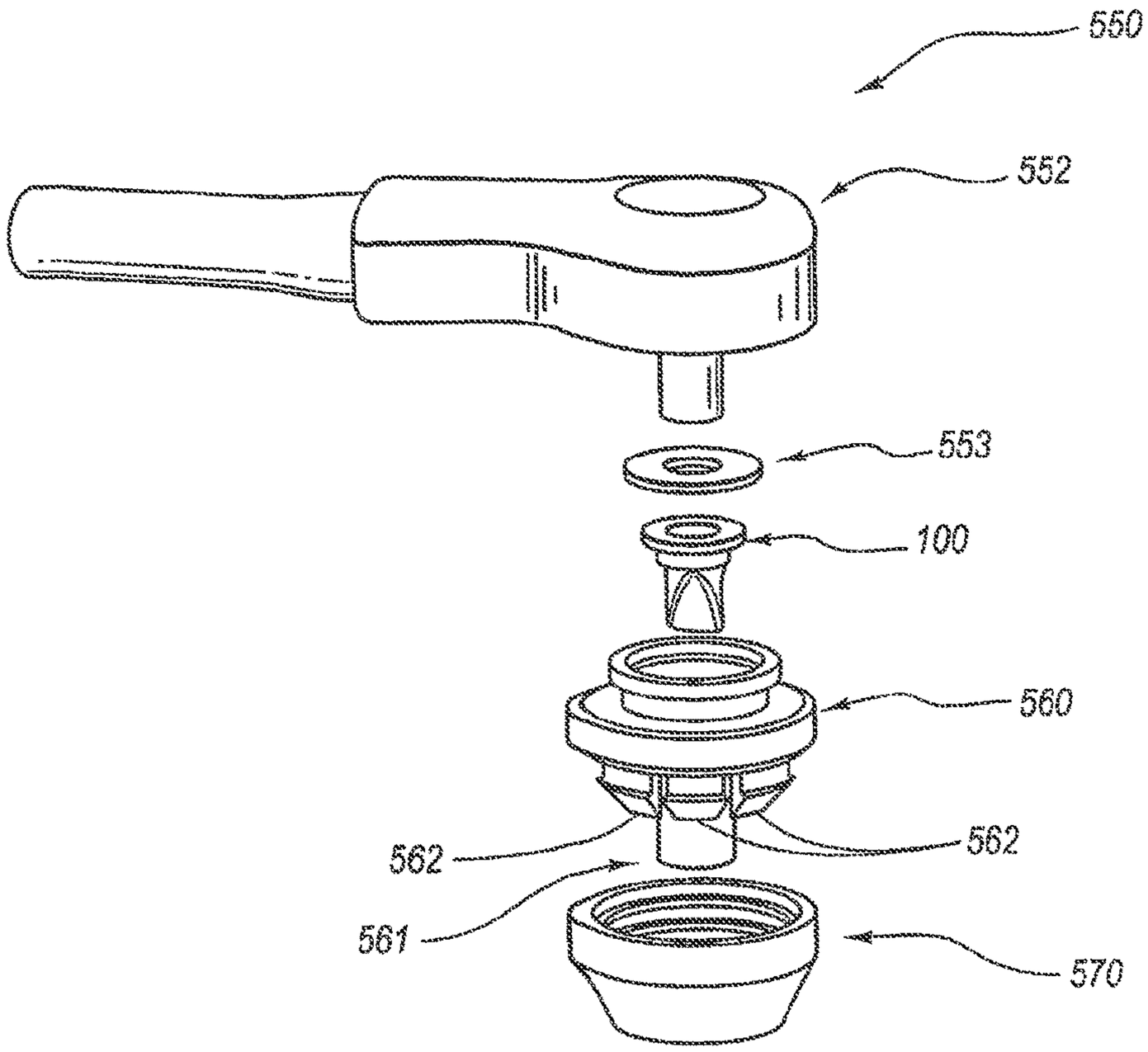

550
552
553
100
560
562
562
561
570

FIG. 27

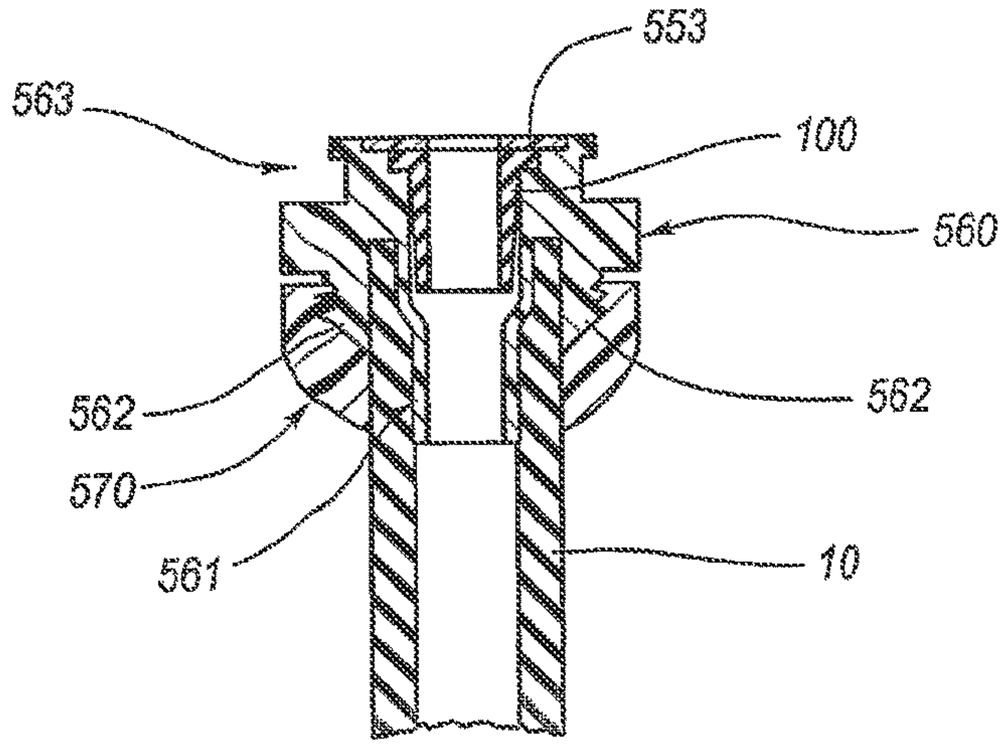

553
563
100
560
562
562
570
561
10

FIG. 28

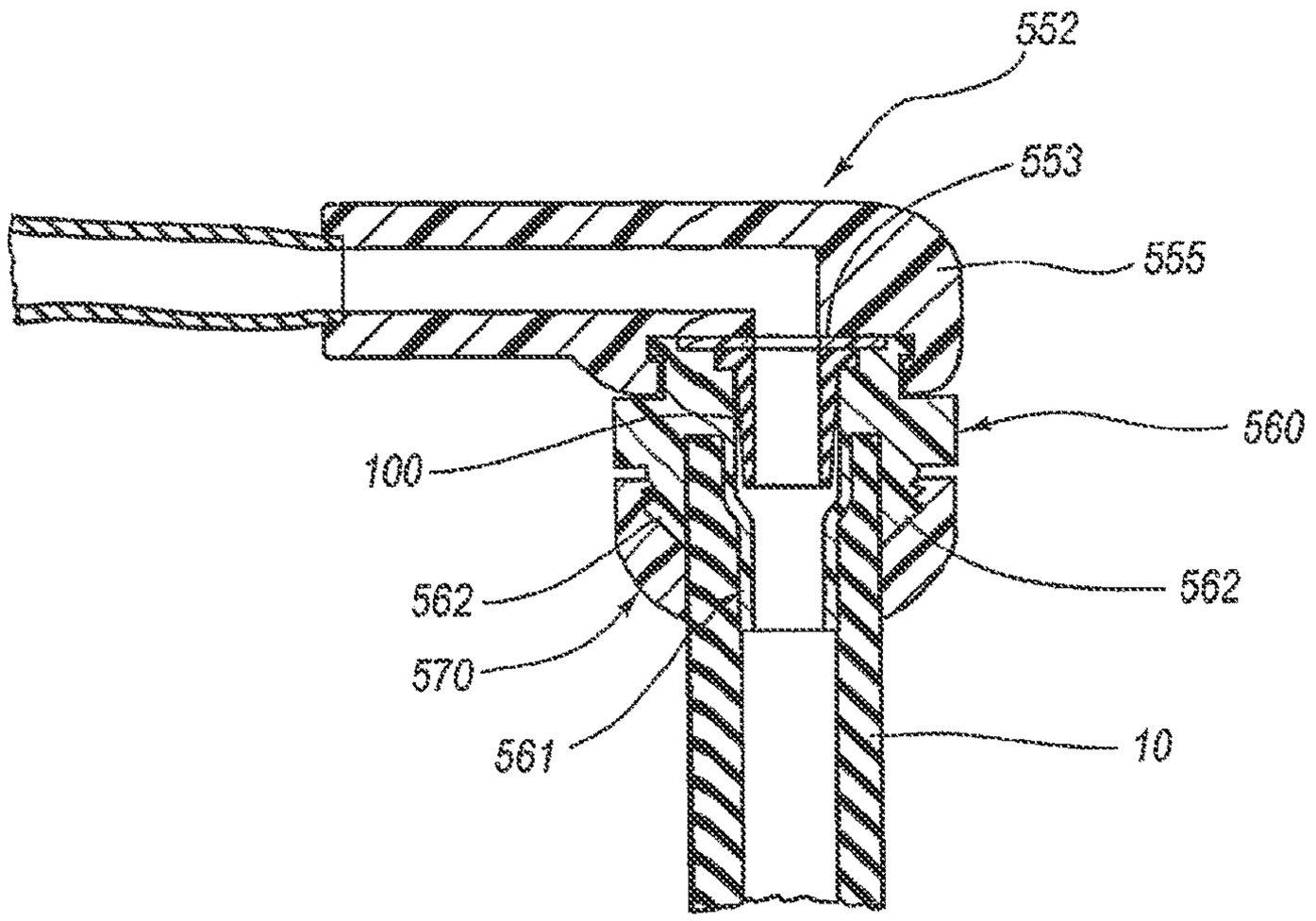

552
553
555
560
100
562
562
570
561
10

FIG. 29

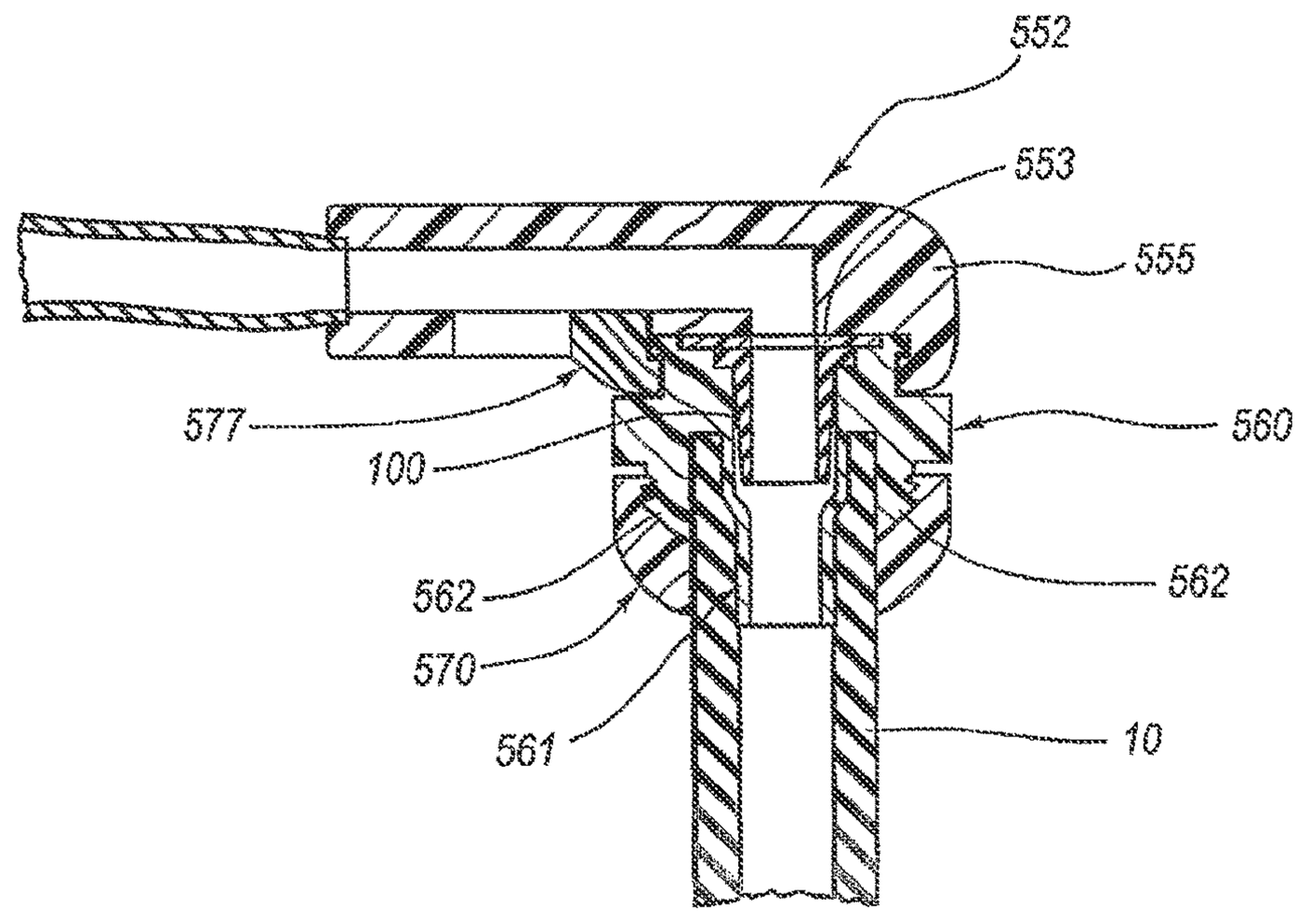

552
553
555
577
560
100
562
562
570
561
10

FIG. 30

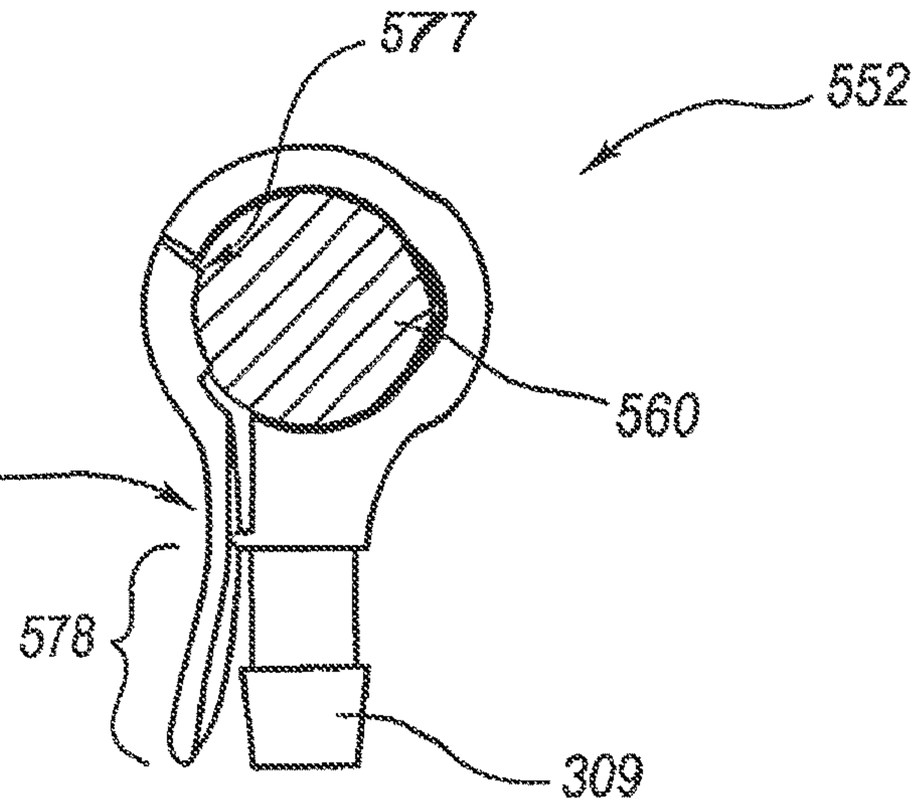


FIG. 31

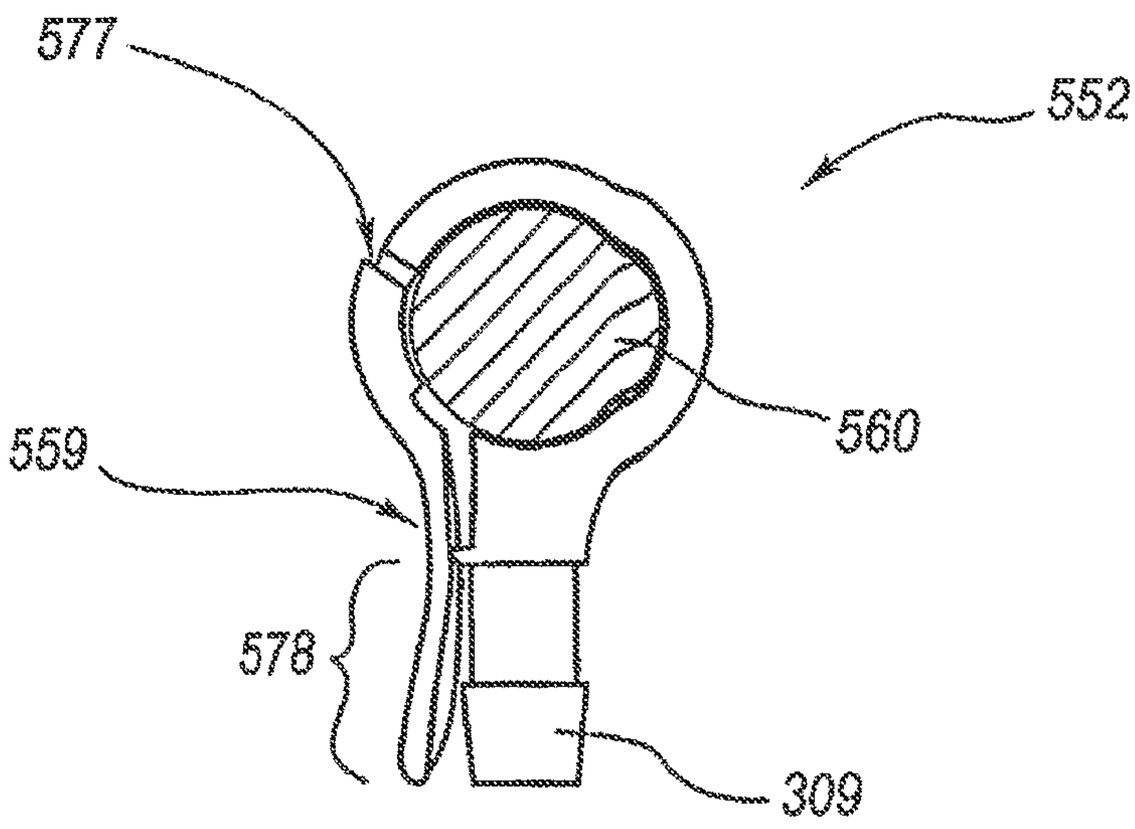


FIG. 32

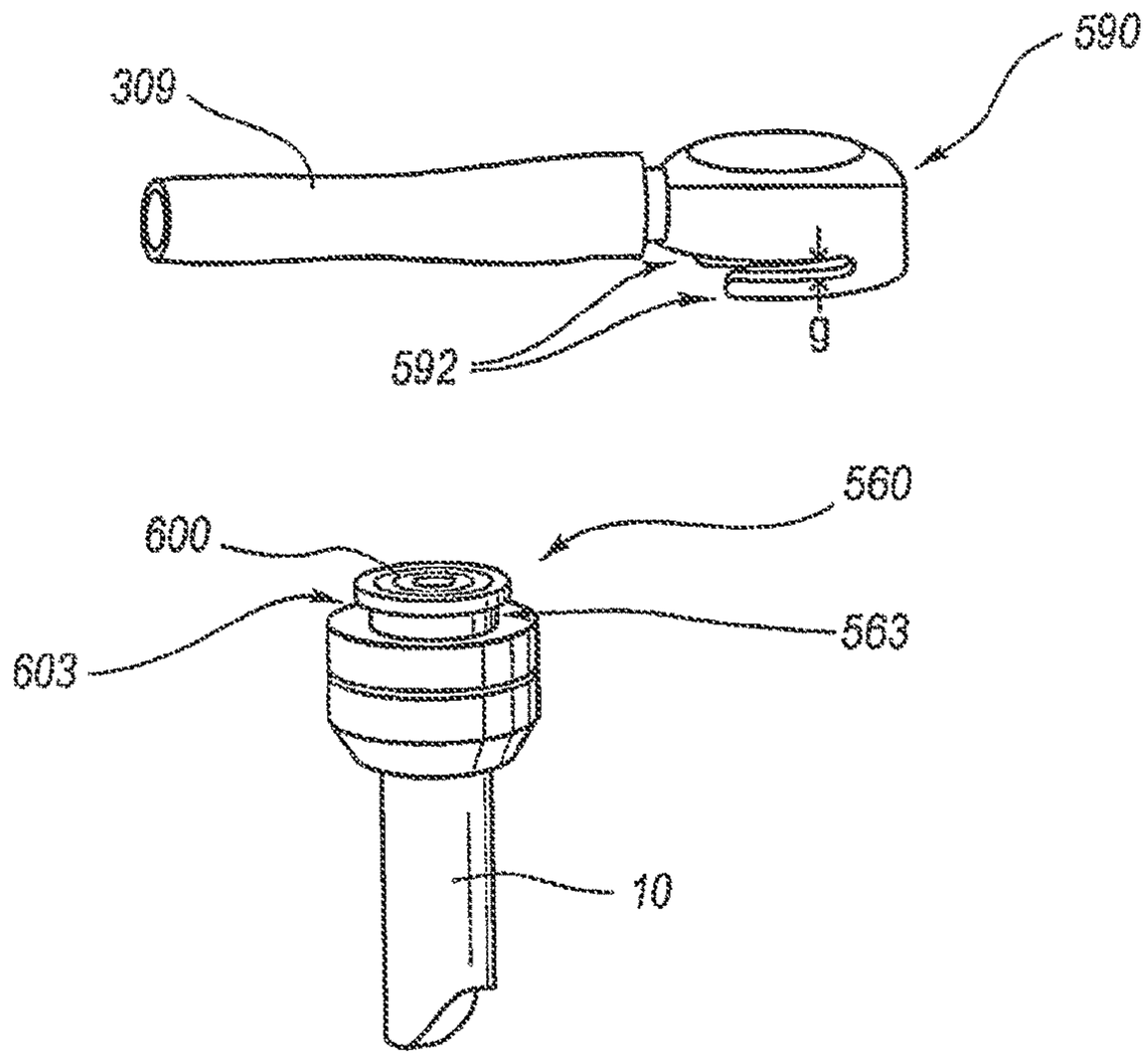


FIG. 33

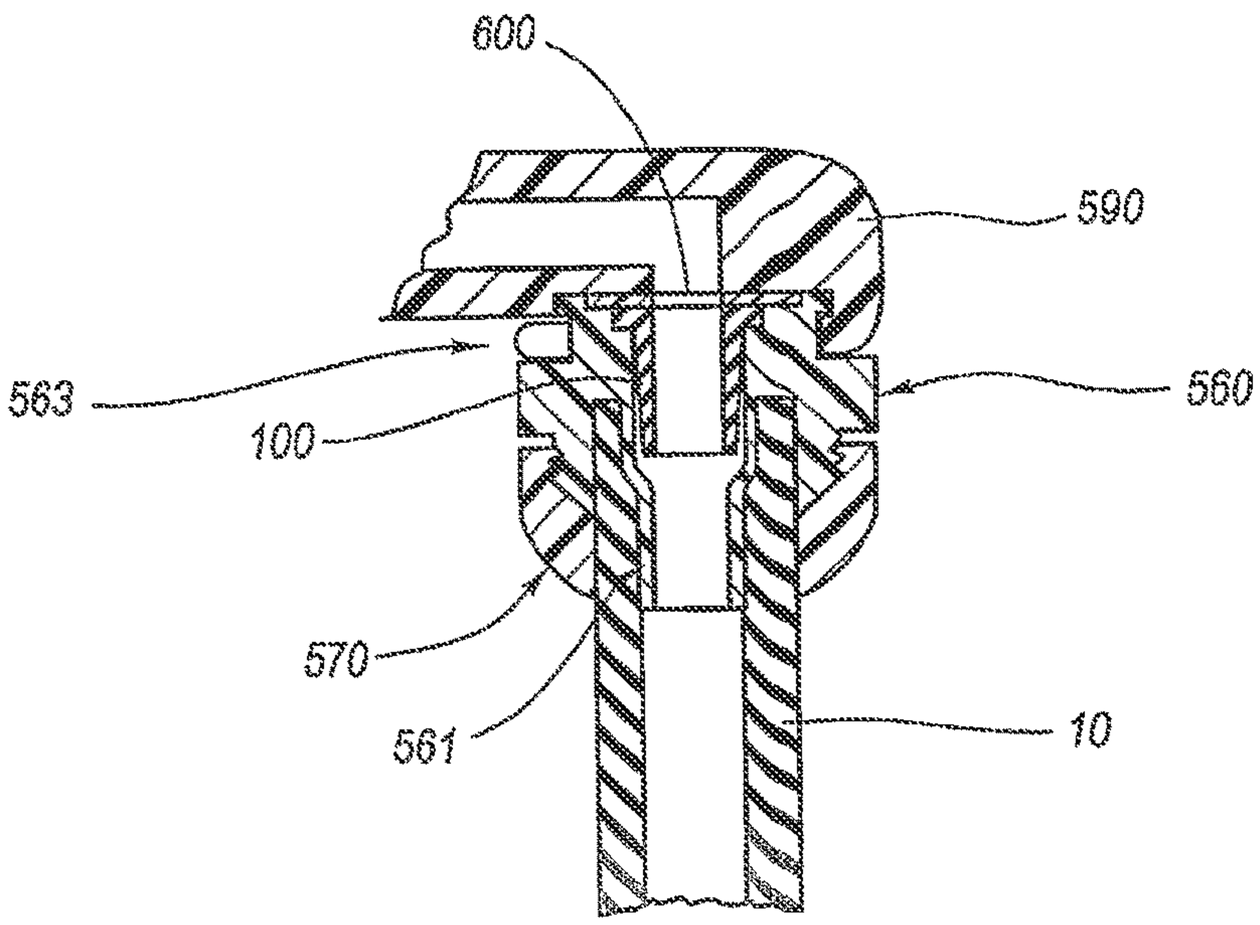


FIG. 34

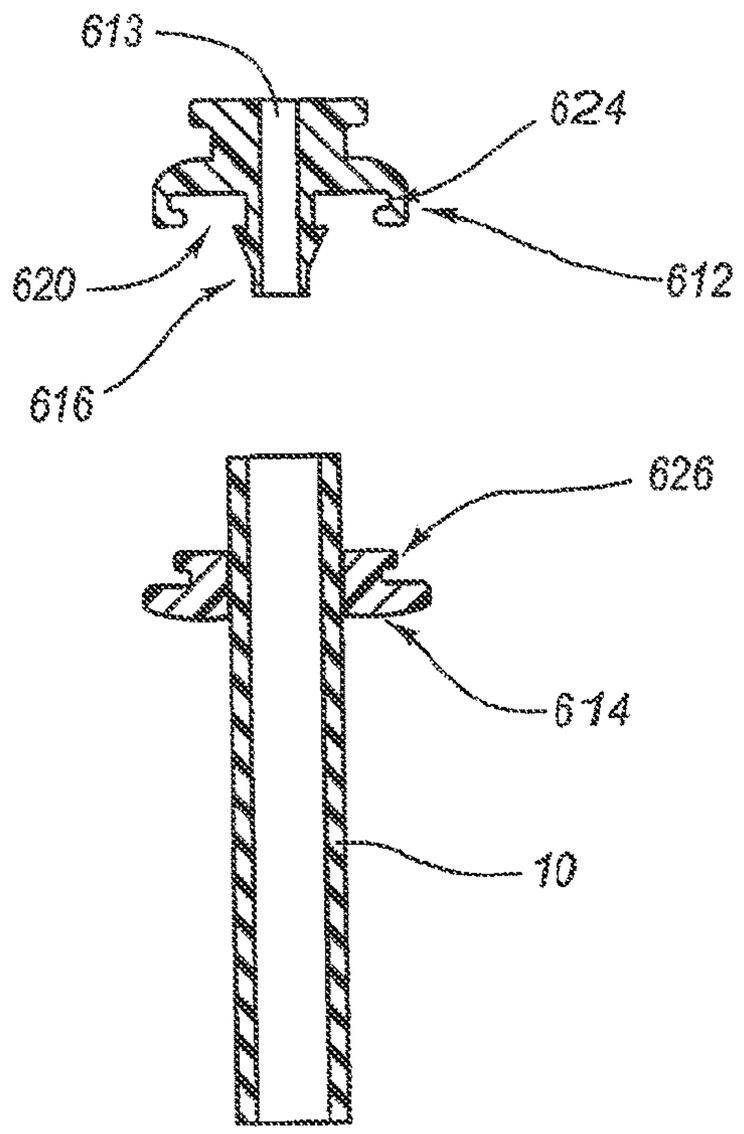


FIG. 35

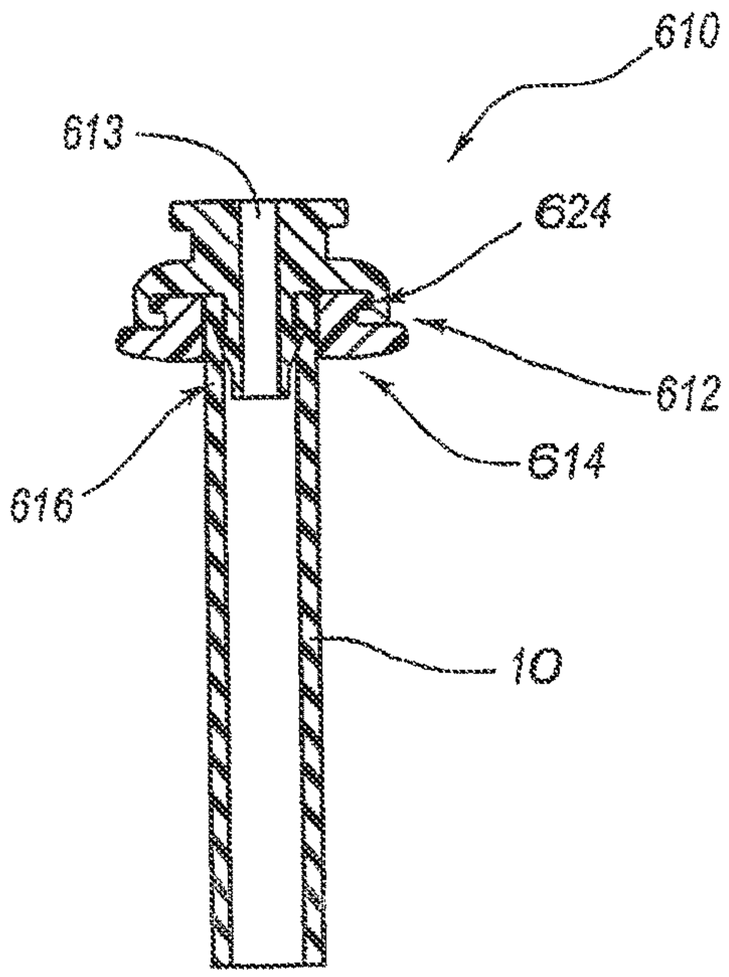


FIG. 36

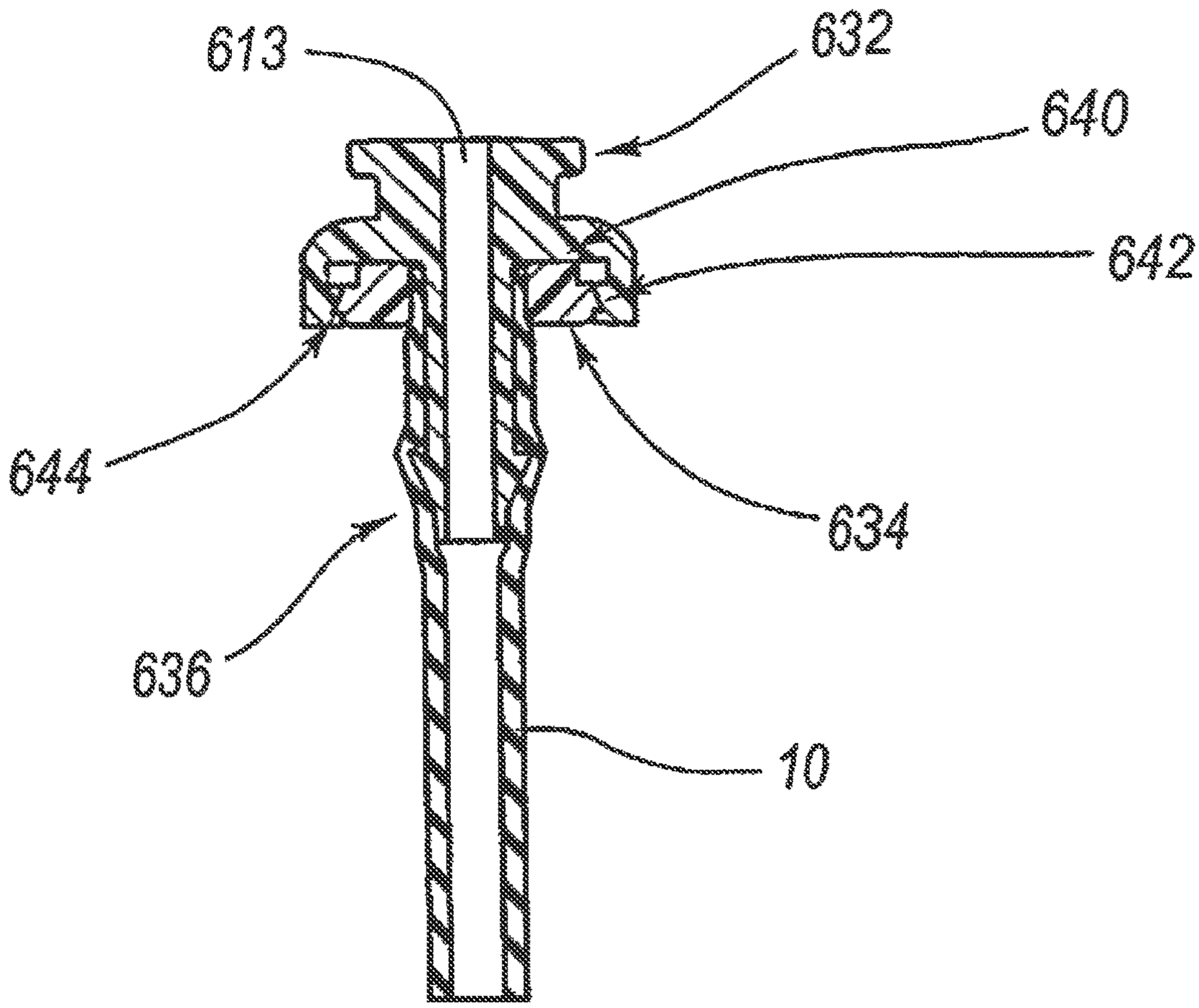


FIG. 37

METHOD AND SYSTEMS FOR PROVIDING FLUID COMMUNICATION WITH A GASTROSTOMY TUBE

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 11/629,724, filed Dec. 15, 2006, now U.S. Pat. No. 8,858,533, which is a U.S. national stage application under 35 U.S.C. §371 of International Application No. PCT/US05/023297, filed Jun. 29, 2005, which claims the benefit of U.S. Provisional Application No. 60/583,703, filed Jun. 29, 2004, the disclosures of each of which is incorporated, in its entirety, by this reference.

BACKGROUND

Gastrostomy is the creation of a temporary or permanent opening between the stomach and the outer skin in the upper abdominal wall. Gastrostomy tubes are indicated for use when a patient cannot be fed by conventional means and long-term gastric access is needed. Nutrition is either fed, through such a gastrostomy tube, to the patient in a single dose (bolus feeding) or over time using a pump (continuous feeding). Also, the patient may require medication that can be administered directly into the patient's stomach using the gastrostomy tube. This is particularly advantageous in patients, especially children, who often dislike the taste of certain medications.

BRIEF SUMMARY

One aspect of the instant disclosure relates to a system for providing fluid communication with a gastrostomy tube. Particularly, a connector is disclosed that may include a stem upon which an end region of a gastrostomy tube is positionable. As may be appreciated, the stem may define a bore for communicating with a lumen defined by the gastrostomy tube. Further, a locking region extending from the connector and proximate to at least a portion of the stem may be configured to be radially inwardly biased to compress at least a portion of the end region of the gastrostomy tube positionable upon the stem.

In a further aspect of the instant disclosure, another embodiment of a system for providing fluid communication with a gastrostomy tube is disclosed. More specifically, such a system may include a stem upon which an end region of a gastrostomy tube is positionable. Also, the system may include a compression structure comprising a plurality of tines adjacent to at least a portion of the stem may be configured to be radially inwardly biased to compress at least a portion of the end region of the gastrostomy tube positionable upon the stem.

In a further embodiment encompassed by the instant disclosure, a system for providing fluid communication with a gastrostomy tube may include a connector comprising a body including a stem upon which an end region of a gastrostomy tube is positionable, wherein the body further includes at least one recess configured to allow access to at least a portion of the stem. In addition, at least one clip may be configured to be positioned within the recess, the at least one clip comprising at least two movable legs, the at least two movable legs configured to compress at least a portion of the end region of the gastrostomy tube positionable upon the stem.

In another aspect of the instant disclosure, a system for providing fluid communication with a gastrostomy tube including a stem upon which an end region of a gastrostomy tube is positionable is disclosed. In addition, the system may include a plurality of physically separate components configured, when assembled to one another, to compress at least a portion of the end region of the gastrostomy tube positionable upon the stem.

Another aspect of the instant disclosure relates to a gastrostomy tube and feeding tube assembly. Particularly, a feeding tube assembly may be capable of selective coupling to an adaptor in fluid communication with an gastrostomy tube and may be rotatable, when coupled to the adaptor, about a longitudinal axis of the adaptor.

The instant disclosure also relates to a method of coupling a stem to a gastrostomy tube. Specifically, a stem may be positioned within an end region of a gastrostomy tube. Also, a plurality of separate components may be positioned proximate to the end region of the gastrostomy tube and assembled to cause radial inward compression of at least a portion of the end region of the gastrostomy tube.

A further method of coupling a stem to a gastrostomy tube relates to positioning a stem within an end region of a gastrostomy tube, positioning a plurality of tines generally about the circumference of the end region of the gastrostomy tube, and radially inwardly biasing the plurality of tines.

Features from any of the above mentioned embodiments may be used in combination with one another, without limitation. In addition, other features and advantages of the instant disclosure will become apparent to those of ordinary skill in the art through consideration of the ensuing description, the accompanying drawings, and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

Further features of the subject matter of the instant disclosure, its nature, and various advantages will be more apparent from the following detailed description and the accompanying drawings, which illustrate various exemplary embodiments, are representations, and are not necessarily drawn to scale, wherein:

FIG. **1** shows a schematic view of an implanted gastrostomy tube;

FIG. **2** shows a schematic view of a shortened gastrostomy tube including an adaptor coupled thereto;

FIG. **3** shows a schematic view of the shortened gastrostomy tube including an adaptor shown in FIG. **2**, further including a feeding tube assembly;

FIG. **4** shows a cross-sectional view of a gastrostomy tube adaptor;

FIG. **5** shows a partial, schematic, side cross-sectional view of one embodiment of a gastrostomy tube connector;

FIG. **6** shows a partial, schematic, side cross-sectional view of another embodiment of a gastrostomy tube connector;

FIG. **7** shows a partial, schematic, side cross-sectional view of a further embodiment of a gastrostomy tube connector;

FIG. **8** shows a perspective view of an embodiment of a gastrostomy tube adaptor;

FIG. **9** shows a perspective view of another embodiment of a gastrostomy tube adaptor;

FIG. **10** shows a perspective view of a one-way valve;

FIG. **11** shows a perspective view of another embodiment of a one-way valve;

FIG. **12** shows a perspective view of yet a further embodiment of a one-way valve;

FIG. **13** shows a perspective view of a gastrostomy tube adaptor including compression clips;

FIG. **14** shows a perspective view of compression clips positioned about a gastrostomy tube;

FIG. **15** shows a schematic, side cross-sectional view of the adaptor shown in FIG. **13**;

FIG. **16** shows a perspective view of a feeding tube assembly configured to mechanically couple to a gastrostomy tube apparatus;

FIG. **17** shows a perspective view of a base element including a stem and a gastrostomy tube positioned upon the stem;

FIG. **18** shows a perspective view of a clamping apparatus;

FIG. **19** shows a schematic, top-elevation view of the clamping apparatus shown in FIG. **18**;

FIG. **20** shows a schematic, top-elevation view of the clamping apparatus shown in FIG. **18**, when assembled;

FIG. **21** shows a perspective view of a gastrostomy tube assembly including a clamping apparatus as shown in FIGS. **18** through **20**;

FIG. **22** shows a perspective view of another embodiment of a clamping apparatus;

FIG. **23** shows a perspective view of the clamping apparatus shown in FIG. **22** assembled to a base element;

FIG. **24** shows a schematic, side cross-sectional view of the assembly shown in FIG. **23**;

FIG. **25** shows an exploded assembly view of another embodiment of a gastrostomy tube adaptor assembly;

FIG. **26** shows a partial, schematic, side cross-sectional view of the assembly shown in FIG. **25**;

FIG. **27** shows an exploded assembly view of a further embodiment of a gastrostomy tube adaptor assembly;

FIG. **28** shows a partial, schematic, side cross-sectional view of the assembly shown in FIG. **27**;

FIG. **29** shows a schematic, side cross-sectional view of one embodiment of a feeding tube assembly;

FIG. **30** shows a schematic, side cross-sectional view of another embodiment of a feeding tube assembly including a movable locking element;

FIGS. **31** and **32** show different top-elevation views of the feeding tube assembly shown in FIG. **30**;

FIG. **33** shows a perspective view of yet an additional embodiment of a feeding tube assembly;

FIG. **34** shows a schematic, side cross-sectional view of the feeding tube assembly shown in FIG. **33**;

FIG. **35** shows a schematic view of a gastrostomy tube adaptor including a base element and a pliant ring;

FIG. **36** shows a schematic view of the gastrostomy tube adaptor shown in FIG. **35**, in unassembled state; and

FIG. **37** shows a schematic, side cross-sectional view of a further embodiment of a gastrostomy tube adaptor.

DETAILED DESCRIPTION

Systems, apparatuses, and methods for operably coupling to an implanted gastrostomy tube are disclosed. More particularly, an apparatus or system that may be coupled to an implanted gastrostomy tube to provide fluid communication with such gastrostomy tube is encompassed by the instant disclosure. For example, in one embodiment, FIG. **1** shows a gastrostomy tube **10** that has been implanted within a patient and has a length of between approximately eight to approximately twelve inches of tubing extending from the surface of the patient's abdomen. A gastrostomy tube having such a length may be helpful in clinical environments where a nurse may need to frequently access the device without disturbing the patient. As shown in FIG. **1**, the gastrostomy tube **10** may be initially coupled to a patient by an internal bolster **20** and an external bolster **12**, which may facilitate creation of and maintain a stoma tract **22** formed between the abdominal wall **18** and the stomach wall **26**. As mentioned above, a gastrostomy tube **10** having a relatively long length (e.g., in excess of about six inches extending from the patient) may cause difficulties. For instance, a gastrostomy tube **10** exhibiting a relatively long length may invite removal of the gastrostomy tube **10**, particularly if the patient is prone to disturb or dislodge the gastrostomy tube **10** from the stoma, or if the gastrostomy tube **10** becomes caught on something and is inadvertently removed. Therefore, especially if the patient is ambulatory, a shorter gastrostomy tube **10** may be more comfortable and less troublesome. Thus, the instant disclosure contemplates that the gastrostomy tube **10**, as shown in FIG. **1**, may be shortened and operably coupled to an apparatus or system encompassed by the instant disclosure. Optionally, such coupling may occur after an adhesion or stoma tract **22** forms between an abdominal wall **18** and a stomach wall **26** of a patient.

Explaining further, conceptually, gastrostomy tube **10** may be shortened (e.g., after a stoma tract forms between an abdominal wall and a stomach of a patient) and an apparatus may be coupled to the shortened gastrostomy tube **10** to provide for fluid communication with the shortened gastrostomy tube. FIG. **2** shows a schematic representation of a shortened gastrostomy tube **10** including an adaptor **28** coupled thereto. A selected, shortened length of the gastrostomy tube **10**, as shown in FIG. **2**, may provide a gap **29** between the skin surface "S" of the patient and the exposed length of the gastrostomy tube **10**. In addition, FIG. **3** shows a schematic representation of the shortened gastrostomy tube **10** including a feeding tube assembly **32** and feeding tube **30** operably coupled to the adaptor **28**. Such a method and adaptor **28** may allow for fluid communication between the feeding tube **30** and the gastrostomy tube **10** and may also provide a relatively "low-profile" feeding tube system for long term use, without removing the initially implanted gastrostomy tube **10**.

Generally, a system or apparatus for use with a gastrostomy tube may include a stem that is inserted within a lumen of the gastrostomy tube. For example, in one embodiment, FIG. **4** shows a cross-sectional view of an adaptor **80** comprising a connector **90** including a stem **120**, which may, optionally, include at least one barb feature **122**, inserted within a lumen of a gastrostomy tube **10**. In addition, adaptor **80** includes a one-way valve **100** positioned within a bore of the connector **90** and a compression sleeve **140** positioned about the connector **90**. One-way valve **100** is shown embodying a so-called "duckbill" or Heimlich valve; however, other types of one-way valves (flapper-type, ball-type, etc.), as known in the art, may be employed for controlling fluid communication with gastrostomy tube **10**. Such a one-way valve may be configured to prevent reflux (e.g., gastric liquid or gas) from exiting the gastrostomy tube **10** from a stomach. The connector **90**, as shown in FIG. **4**, also includes locking region **130**, which is configured to be radially displaced or biased toward the gastrostomy tube **10** to compress the gastrostomy tube **10** between a portion of the stem **120** and the locking region **130**. In one embodiment, locking region **130** may comprise a plurality of circumferentially-spaced (about the stem **120**) tines or prongs (e.g., a collet or similar structure) or, in another embodiment, locking region **130** may comprise a substantially tubular shape. Explaining further, the compression sleeve **140** may be positioned about the locking region **130**

of the connector **90** and may be configured to generate a radially inward force upon the locking region **130**. Such a radially inward force may, in turn, bias at least a portion of the locking region **130** toward the gastrostomy tube **10** to effectively couple the gastrostomy tube **10** to the stem **120**. Optionally, as shown in FIG. **4**, stem **120** may include at least one barb **122**. Further, a connector cap **144** may be affixed to compression sleeve **90** by way of a connection structure **145** (e.g., a so-called luer connection or any other connection structure as known in the art) or, such a feature may be incorporated into the connector **90**. In another embodiment, compression sleeve **140** and connector cap **144** may be combined into a single piece. Further, an engagement structure **134** (shown in FIG. **4** as a recessed region) may comprise a so-called snap-lock, threaded connection, or any other connection structure as known in the art. Engagement structure **134** may be formed in connector cap **144**, connector **90**, or compression sleeve **140** and may be configured to operably couple a feeding tube to the adaptor **80**. During use, a feeding tube extension or assembly may be coupled to the adaptor **80** by contact with tapered surface **88** of one-way valve **100**. Optionally, a sealing element (e.g., an O-ring) may be positioned between tapered surface **88** and a surface of a feeding tube assembly to provide a fluid-tight (i.e., hydraulic, pneumatic, or both hydraulic and pneumatic) seal between the surfaces. Such contact may also cause the one-way valve **100** to at least partially open; thus, fluid communication through the one-way valve may be facilitated. A closure element **180** may be employed to close the interior bore of the adaptor **80** while not in use.

FIG. **5** shows a partial, schematic, side cross-sectional view of another embodiment of connector **90**, particularly, stem **120** and locking region **130**. The locking region **130**, as shown in FIG. **5**, has at least one tapered feature **190** configured to interfere with an interior surface of compression sleeve **140** (FIG. **4**) when the compression sleeve **140** (FIG. **4**) is assembled to the connector **90**. Accordingly, such interference may cause the locking region **130** to be deformed or displaced radially inwardly, as discussed above. In addition, at least one protrusion **192** may be formed upon locking region **130**. Protrusion **192** may extend generally radially inwardly and may be generally pointed, as shown in FIG. **5**. Such a configuration may facilitate locking of a gastrostomy tube **10** (FIG. **4**) upon the stem **120**. The instant disclosure further contemplates that a plurality of barbs may be formed, at selected positions and having selected configurations, respectively, on the stem **120** and may allow for formation of a robust mechanical and fluid-tight coupling between a gastrostomy tube **10** (FIG. **4**) and a bore **121** defined by the stem **120**.

In a further aspect of the instant disclosure, at least one protrusion formed upon a locking region of a connector may be positioned proximate to a maximum radial extent of a barb formed on a stem of a connector. For example, in one embodiment, FIG. **6** shows a partial, schematic, side cross-sectional view of a stem **120** that has a barb **122** that includes a maximum radial extent located at a longitudinal position "L1" (with respect to a longitudinal axis **11** of stem **120**) from a distal surface **194** of the connector **90**. Further, protrusion **192** may be located proximate to the maximum radial extent of barb **122**. Also, as shown in FIG. **6**, protrusion **192** may be located at a longitudinal distance from distal surface **194** of connector **90** that exceeds the longitudinal distance between the maximum radial extent of barb **122** and distal surface **194** of connector **90**. Such a configuration may provide a relatively robust coupling and fluid-tight connection between the bore **121** defined by stem **120** and the gastrostomy tube **10**. As illustrated in FIGS. **4-6** the locking region **130** extends from and is integral with the connector **90**.

In another embodiment, at least one protrusion formed upon a locking region of a connector may be positioned proximate to a distal surface of the connector. For example, in one embodiment, FIG. **7** shows a partial, schematic, side cross-sectional view of a locking region **130** that has a barb **122**. Further, protrusion **192** may be located proximate to the distal surface **194** of the connector **90**. Also, as shown in FIG. **7**, protrusion **192** may be located at a longitudinal distance "L2" from distal surface **194** of connector **90** that is less than the longitudinal distance between the maximum radial extent of barb **122** and distal surface **194** of connector **90**. Such a configuration may provide a relatively robust coupling and fluid-tight connection between the bore **121** defined by stem **120** and the gastrostomy tube **10**.

FIG. **8** shows a perspective view of an embodiment of an adaptor **280**. More specifically, adaptor **280** may be configured generally as described above in relation to adaptor **80**, but may also include an angled portion **222** (e.g., forming a right angle with respect to a longitudinal axis of the gastrostomy tube **10**). As described above, locking region **130** may be compressed toward the gastrostomy tube **10** by a compression sleeve **220**. Since compression sleeve **220** may be difficult to position over angled portion **222** of adaptor **280**, compression sleeve **220** may be embody a clam-shell design or may be separate pieces that lock or interconnect to one another around gastrostomy tube **10**, subsequent to positioning of a stem of adaptor **280** within gastrostomy tube **10**, as discussed below. Of course, adaptor **280** may also include a one-way valve, as discussed above, and may include features that to allow attachment of a straight feeding tube to port opening **282** to achieve a low-profile design. FIG. **9** shows a perspective view of another embodiment of an angled portion **222** of an adaptor including a threaded port **240** and a threaded housing **250** for attachment to the threaded port **240**. Further, threaded housing **250** may include a one-way valve. Such a configuration may be desirable so that the one-way valve may be removed and replaced if needed.

In further detail, FIG. **10** shows a one-way valve **101** in a perspective view that comprises a frame element **348** (e.g., a substantially cylindrical frame) defining an opening **345** and including a first flap **342** extending over about half of the cross-sectional area of the opening **345** and a second flap **344** extending over the remaining cross-sectional area of the opening **345**. Further, first flap **342** and second flap **344** may contact one another along mating line **340** (i.e., a slit) and may be configured to generally resist the flow of fluid between first flap **342** and second flap **344**. However, one-way valve **101** may be configured so that fluid flow is allowed between first flap **342** and second flap **344** (through slit or mating line **340**) when a syringe or other suitably shaped device applies a force to flaps **342** and **344**. Thus, a syringe may engage flaps **342** and **344** so that the edges (forming mating line **340**), respectively, separate from one another to allow fluid flow between flaps **342** and **344**. FIG. **11** shows a perspective view of another embodiment of a one-way valve **103**, configured as a duckbill valve, including protruding feature **356**, which is separated, at its distal end, along mating line **350** into a first half **352** and a second half **354**. Similar to one-way valve **101**, first half **352** and second half **354** are configured to prevent fluid flow there-between (i.e., along mating line **350**), unless a syringe or other suitably shaped device contacts the first half **352** and second half **354**. In yet a further embodiment of a one-way valve,

FIG. **12** shows a perspective view of another one-way valve **105** (configured as a duckbill valve) including a land area **360** of protruding feature **356** having a length "L" and concave side surfaces **355** and **353**. Repeated use and stresses in the material forming one-way valve **105** may cause the mating line **350** to remain at least partially open due to the material "creep" or permanent deformation, as known in the art. Configuring the side surfaces **353** and **355** to exhibit a concave shape may resist such material creep and may also facilitate or bias the one-way valve **105** to close.

FIG. **13** shows a perspective view of a further embodiment of an adaptor **300** including an outlet port **270** that forms an angle (i.e., is not generally aligned with) with respect to a gastrostomy tube **10** to which it is coupled. In addition, recess **294** may be formed laterally (i.e., substantially perpendicular to a longitudinal axis of gastrostomy tube **10**) through the body of adaptor **300** to allow access to the end region of gastrostomy tube **10** positioned upon a stem (discussed below) of the adaptor **300**. As shown in FIG. **13**, compression clip **292** (and compression clip **290** shown in FIGS. **14** and **15**, discussed below) may be positioned within recess **294** and may radially inwardly compress and mechanically couple gastrostomy tube **10** to the adaptor **300**. In further detail, FIG. **14** shows a perspective view of compression clips **290** and **292** positioned about gastrostomy tube **10** and stem **301** of adaptor **300**. As shown in FIG. **14**, compression clip **292** may include a pair of upper movable arms **296** and a pair of lower movable arms **296**, wherein each set of movable arms has an arcuate surface for contacting at least a portion of the gastrostomy tube **10** to compress the portion of the gastrostomy tube **10** radially inwardly against stem **301**. Also as shown in FIG. **14**, compression clip **290** may include a pair of movable arms **297** and may be positioned longitudinally between the upper and lower pair of movable arms **296** of compression clip **292**. FIG. **15** shows a schematic side cross-sectional view of adaptor **300** illustrating the location of compression clips **290** and **292** positioned within recess **294** and about gastrostomy tube **10** and stem **301**.

FIG. **16** shows a perspective view of a feeding tube assembly **306** including a coupler **304** with a radially protruding feature **302** and a stem portion **305** and feeding tube **309** extending from the stem portion **305**. Coupler **304** may be configured for mechanically coupling to a connector **312** (e.g., connector **90** as discussed above or a base element as discussed below). More particularly, protruding feature **302** may align with groove **310** formed in recess **307** of the connector **312**. Further, protruding feature **302** may fit into or otherwise engage a lip or other feature (e.g., another recess such as recess **134** as shown in FIG. **4**) formed into the surface of recess **307**.

Another aspect of the instant disclosure relates to a gastrostomy tube adaptor that has a clamping mechanism that may be installed upon a base element including a stem. More particularly, a clamping mechanism may be configured to at least partially circumferentially contact and correspondingly radially compress a gastrostomy tube onto a stem of the base element. For example, a clamping mechanism may include two separate pieces that couple to one another to compress a gastrostomy tube onto a stem of the base element. More generally, a system for providing fluid communication with a gastrostomy tube may include a plurality of separate pieces, which, when assembled, are configured to compress at least a portion of an end region of a gastrostomy tube positionable upon a stem. Such a configuration may simplify the design of an adaptor for converting a gastrostomy tube to a low-profile in comparison to the adaptor described above including a connector with a locking region. Explaining further, a common base element may be used in combination with a selected clamping apparatus to provide flexibility. In one embodiment, FIG. **17** shows a perspective view of base element **450** including a stem **460** positioned within a gastrostomy tube **10**. Bore **451** of base element **450** is in fluid communication with the lumen of gastrostomy tube **10**. As explained below, a feeding tube may be selectively coupled to base element **450** and may be used to provide nourishment into a stomach of a patient through the gastrostomy tube **10**.

FIG. **18** shows a perspective view of a clamping apparatus **410** including a first half **412** and a second half **414**. First half **412** includes locking arms **416**, each of locking arms **416** including a protruding feature **417** for engaging a suitably shaped engagement surface **423** formed in grooves **422** of second half **414**. First half **412** and second half **414** may each include an arcuate surface **418**, **420**, respectively, configured for compressing a portion of a gastrostomy tube positioned upon a stem about which the clamping apparatus **410** is positioned. In further detail, FIG. **19** shows a schematic, top-elevation view of clamping apparatus **410** positioned about gastrostomy tube **10** and stem **460**. As may be appreciated, upon movement of first half **412** and second half **414** toward one another, protruding features **417** may move along tapered regions **419**, respectively, and may effectively lockingly engage engagement surfaces **423** of second half **414**. FIG. **20** shows a schematic, top-elevation view of first half **412** and second half **414** coupled to one another via protruding features **417** engaging engagement surfaces **423**. In addition, it may be appreciated that the gastrostomy tube **10** may be compressed by the arcuate surfaces **418**, **420** (shown as substantially semi-cylindrical in FIGS. **18** and **19**) against stem **460**. FIG. **21** shows a perspective view of a gastrostomy tube assembly **408** including the clamping apparatus **410** installed upon base element **450** including stem **460** positioned within gastrostomy tube **10**. Optionally, a closure element **452** may be coupled to the base element **450** to close the bore extending therethrough. Also, optionally, a one-way valve may be positioned within the base element **450**. The first half **412** of the system and the second half **414** of the system may include complementary locking features, e.g., protruding features **417**, configured to engage one another to form a circular arcuate surface **418**, **420**.

FIG. **22** shows a perspective view of another embodiment of a clamping apparatus **404** including a hinge mechanism **430**, clamp elements **432**, **433**, and halves **437**, **439**. More specifically, halves **437**, **439** may comprise a pliant material such as silicone, while clamp elements **432**, **433** may comprise a relatively rigid material such as a rigid plastic (e.g., polyethylene, polypropylene, etc.) or a metal. Such a configuration may provide a relatively comfortable gastrostomy tube apparatus for a patient's use. Optionally, halves **437**, **439** may substantially surround clamp elements **432**, **433**. Arcuate surfaces **448**, **446** (shown as substantially semi-cylindrical) of clamp elements **432**, **433** may be configured for compressing a gastrostomy tube against a stem about which the clamping apparatus **404** is positioned. Annular recess **436** may be configured for accepting, upon placement of the clamping apparatus about a gastrostomy tube within which a base element is positioned, a corresponding annular flange of a base element. Thus, each of halves **437**, **439** may be separated by rotation about hinge mechanism **430** and positioned about a gastrostomy tube. As shown in FIG. **22**, clamp element **432** includes a locking

feature **441** that extends from clamp element face **434** for securing clamp element **432** to clamp element **433**. Accordingly, clamp elements **432**, **433** may include complementary locking features (e.g., protruding features, pins, or any other locking features as known in the art) configured to secure clamp elements **432**, **433** to one another. FIG. **23** shows a perspective view of clamping apparatus **404** assembled to the base element **450**. Further, FIG. **24** shows a schematic side cross-sectional view of clamping apparatus **404** assembled to base element **450**. As shown in FIG. **24**, clamping elements **432**, **433** may be configured to compress gastrostomy tube **10** onto stem **460** of base element **450**. Thus, bore **451** of base element **450** may be in fluid communication with a lumen of gastrostomy tube **10**. Optionally, base element **450** may be configured to accept a one-way valve configured to allow fluid to flow in a direction toward or into gastrostomy tube **10**, but inhibit fluid flow from gastrostomy tube **10** toward base element **450**. The first half **437** of the system and the second half **439** of the system may include complementary locking features configured to engage one another to form a circular arcuate surface **446**, **448**.

FIG. **25** shows an exploded assembly view of another embodiment of a gastrostomy tube adaptor assembly **510** including feeding tube assembly **502**, locking hub **504**, one-way valve **100**, base element **506**, and compression ring **508**. In further detail, a gastrostomy tube may be positioned about stem **501** of base element **506** and locking elements **514** of locking hub **504** may each engage a complementary engagement feature formed within compression ring **508**. More specifically, longitudinal movement between locking hub **504** and compression ring **508** may cause locking elements **514** to engage or otherwise be retained by a complementary engagement feature formed within compression ring **508**. Also, regions **520** may be configured to move locking elements **514** inwardly upon application of force thereon (e.g., by squeezing of a hand of a user) to release each of the locking elements **514** from a respective complementary engagement feature formed within compression ring **508**. Further, compression ring **508** may be configured to compress (e.g., radially inwardly compress) a gastrostomy tube positioned between the compression ring **508** and the stem **501** of the base element **506**. For example, FIG. **26** shows a schematic side cross-sectional view of an assembly of locking hub **504**, one-way valve **100**, base element **506**, and compression ring **508**, as shown in FIG. **25**. As shown in FIG. **26**, locking hub **504** includes an annular recess **505** configured for engaging locking features **512** (FIG. **25**) of feeding tube assembly **502** (FIG. **25**). Such a configuration, when locking hub **504** and feeding tube assembly **502** (FIG. **25**) are coupled to one another, may allow for rotation of feeding tube assembly **502** (FIG. **25**) with respect to locking hub **504**. Also, pressure applied generally to region **509** (FIG. **25**) may cause locking feature **512** to release from annular recess **505**. Thus, feeding tube assembly **502** (FIG. **25**) may be selectively released from locking hub **504** when desired. Also, as shown in FIG. **26**, compression ring **508** may be configured for inwardly radially compressing at least a portion of an end region of gastrostomy tube **10** positioned upon stem **501** of base element **506**.

FIG. **27** shows an exploded assembly view of a gastrostomy tube adaptor assembly **550** including feeding tube assembly **552**, washer element **553**, one-way valve **100**, base element **560**, and compression ring **570**. More specifically, as shown in FIG. **27**, base element **560** includes tines **562** extending longitudinally from base element **560** that have a threaded exterior surface. Tines **562** extend from base **560** proximate to stem **561** and may be configured to be radially inwardly biased to compress at least a portion of an end region of a gastrostomy tube positioned about stem **561** of base element **560**. Thus, compression ring **570** may include a threaded interior surface for threading along the threaded exterior surface of tines **562** so that tines **562** are biased radially inwardly. Thus, FIG. **28** shows a schematic side cross-sectional view of base element **560**, washer element **553**, one-way valve **100**, compression ring **570**, and gastrostomy tube **10**. As shown in FIG. **28**, compression ring **570** may inwardly radially compress tines **562** toward the end region of gastrostomy tube **10** positioned upon stem **561** of base element **560**. Such a configuration may provide an effective and fluid-tight coupling between the base element **560** and the gastrostomy tube **10**. In addition, feeding tube assembly **552** (FIG. **27**) may be configured to couple to base element **560**. In one embodiment, feeding tube assembly **552** (FIG. **27**) may be configured to couple to an annular recess **563** (FIG. **28**) formed in base element **560**. In another embodiment, base element **560** can be configured similarly to region **520**, illustrated in FIG. **25**. In such an embodiment base element **560** can act as a release configured to move the plurality of tines **562** inward upon application of a force to the base element **560**. Force on the release (base element **560**) can release the compression ring **570**, or in another embodiment, a compression sleeve such as compression sleeve **220** illustrated in FIG. **8**.

FIG. **29** shows one embodiment of feeding tube assembly **552** including a cap body **555** comprising a pliant material that is shaped to substantially conformably accommodate the shape of base element **560** and couple to annular recess **563**. Such a configuration may allow for relatively secure coupling between cap body **555** and base element **560** and may allow selective removal of cap body **555** from base element **560**, when desired. In another embodiment, a movable locking feature may be selectively positioned within or removed from annular recess **563** of base element **560** to allow for coupling or removal of feeding tube assembly **552** to and from base element **560**, respectively. For example, FIG. **30** shows a schematic, side cross-sectional view of a movable locking element **577** that may be selectively positioned within annular recess **563** of base element **560**. In one embodiment, movable locking element **577** may be positionable by way of a handle operable by a user's hand. For example, FIGS. **31** and **32** show, in top-elevation views, respectively, a movable locking element **577** operably coupled to a handle region **578**. As shown in FIG. **31**, locking element **577** may be positioned toward base element **560**, to engage a portion or corresponding feature (e.g., annular recess **563**) of the base element **560**. Also, as shown in FIG. **32**, locking element **577** may be positioned away from base element **560**. It may be appreciated that movement of the locking element **577** between the position shown in FIG. **31** and the position shown in FIG. **32** may be accomplished by application of a force upon handle region **578** to cause the locking element **577** to pivot about a hinge mechanism **559**. Further, of course, locking element **557** may be biased toward the position shown in FIG. **31** (i.e., in a locked position) by a biasing element, the hinge elasticity, or as otherwise known in the art.

In an additional embodiment, a feeding tube assembly may include an open sliding connection structure for coupling to a base element. For example, FIG. **33** shows a perspective view of a feeding tube assembly **590** including legs **592** defining gap "g" within which flange **603** of base element **560** may be positioned. Also, FIG. **34** shows a

schematic side cross-sectional view of feeding tube assembly **590** installed upon base element **560**. As illustrated in FIGS. **33-34**, feeding tube assembly **590** may be selectively coupled to gastrostomy tube **10** through base element **560**. Base element **560** acts as an adapter allowing connection of the feeding tube assembly and gastrostomy tube **10**. As may be appreciated, feeding tube assembly **590** may slide onto base element **560** so that legs **592** (FIG. **33**) are positioned within a portion of annular recess **563** (extending on opposite sides of annular recess **563**). Such a configuration may allow for rotation of feeding tube assembly **590** (about a longitudinal axis of base element **560**). In addition, a sealing element **600** may be configured to seal between the base element **560** and the feeding tube assembly **590**, as shown in FIG. **34**. Accordingly, the example feeding tube assembly **590** illustrated in FIGS. **33-34** may be capable of selectively coupling to a compression structure (sealing element **600**) and rotatable, when coupled to the compression structure, about a longitudinal axis of the compression structure. Such a configuration may provide a relatively robust and easy to use gastrostomy tube apparatus or system.

In a further embodiment, a pliant ring, made from a pliant material, may be compressed by a base element to compress a portion of a gastrostomy tube positioned over a stem extending from the base element. For example, in one embodiment, FIG. **35** shows a schematic view of a pliant ring **614**, which can act as a compression ring, positioned about a gastrostomy tube **10** and a base element **612** including a stem **616** configured for positioning within the lumen defined by gastrostomy tube **10**. As shown in FIG. **35**, base element **612** includes a recess **620** configured for accepting pliant ring **614**. Further, recess **620** and pliant ring **614** are configured to compress at least a portion of an end region of gastrostomy tube **10** positioned upon stem **616** of base element **612**. Also, as shown in FIG. **35**, pliant ring **614** (the compression ring) includes annular flange **626** configured to fit and be positioned within annular recess **624** of base element **612**. More specifically, as shown in FIG. **36**, the gastrostomy tube adaptor **610** can include pliant ring **614** may be assembled to base element **612**. Such a configuration may compress at least a portion of gastrostomy tube **10** onto stem **616** and may effectively provide fluid communication between a bore **613** of base element **612** and the lumen of gastrostomy tube **10**. Accordingly, as illustrated in FIGS. **35-36**, recess **620** of base element **612** may be defined by a lip (near **624**) that further includes a second recess, annular recess **624**. The second recess **624** may engage the flange **626** of the compression ring (pliant ring **614**). In another embodiment, FIG. **37** shows a base element **632** having a recess **640** configured for accepting pliant ring **634**. A protrusion **644** (e.g., an annular protrusion) may extend from pliant ring **634** and may engage a recess **642** (e.g., an annular recess) formed in base element **632**. A rim **644**, formed by recess **642** may hold pliant ring **634** in place. Such a configuration may couple pliant ring **634** to base element **632**. In addition, at least a portion of an end region of gastrostomy tube **10** may be compressed between stem **636** of base element **632** and pliant ring **634**.

Although the apparatuses and systems described above have been discussed in the context of low-profile gastrostomy feeding tube embodiments, it should be understood that such apparatuses and systems are not limited to low-profile use and could be used with a gastrostomy feeding tube in any (e.g., high-profile) arrangement, if desired, without limitation. Moreover, such apparatuses and systems are not limited to use with gastrostomy feeding tubes and may be used with various other medical catheters, including drainage catheters, without limitation.

While certain embodiments and details have been included herein for purposes of illustrating aspects of the instant disclosure, it will be apparent to those skilled in the art that various changes in the systems, apparatuses, and methods disclosed herein may be made without departing from the scope of the instant disclosure, which is defined, in part, in the appended claims. The words "including" and "having," as used herein including the claims, shall have the same meaning as the word "comprising."

What is claimed is:

1. A gastrostomy tube adaptor assembly, comprising:

a locking hub, including one or more locking elements;

a feeding tube assembly, configured for rotational attachment to the locking hub;

a base element, including a distally extending stem configured for insertion into a gastrostomy tube, the base element including a discontinuous flange about a proximal end, the discontinuous flange including one or more gaps corresponding to the one or more locking elements;

a one way valve positioned in a lumen of the base element; and

a compression structure, including one or more engagement features configured to engage the one or more locking elements, the gastrostomy tube compressed between the compression structure and the stem when the one or more engagement features engage the one or more locking elements.

2. The gastrostomy tube adaptor assembly according to claim **1**, wherein the one or more locking elements each include a decoupling tab such that movement of the decoupling tab in a radially inward direction releases the one or more locking elements from the one or more engagement features of the compression structure.

3. The gastrostomy tube adaptor assembly according to claim **1**, wherein the locking hub includes an annular recess for receipt of a feeding tube assembly protrusion.

4. The gastrostomy tube adaptor assembly according to claim **3**, wherein the feeding tube assembly protrusion is connected to a release feature such that activation of the release feature detaches the feeding tube assembly from the locking hub.

5. A gastrostomy tube adaptor assembly, comprising:

a locking hub, including one or more locking elements;

a feeding tube assembly, configured for rotational attachment to the locking hub;

a base element, including a distally extending stem configured for insertion into a gastrostomy tube;

a one way valve positioned in a lumen of the base element; and

a compression structure, including one or more engagement features configured to engage the one or more locking elements, the gastrostomy tube compressed between the compression structure and the stem when the one or more engagement features engage the one or more locking elements, the one or more locking elements each including a decoupling tab such that movement of the decoupling tab in a radially inward direction releases the one or more locking elements from the one or more engagement features.

6. The gastrostomy tube adaptor assembly according to claim **5**, wherein the locking hub includes an annular recess for receipt of a feeding tube assembly protrusion.

7. The gastrostomy tube adaptor assembly according to claim **6**, wherein the feeding tube assembly protrusion is

connected to a release feature such that activation of the release feature detaches the feeding tube assembly from the locking hub.

8. A gastrostomy tube adaptor assembly, comprising:

a locking hub, including one or more locking elements and an annular recess;

a feeding tube assembly, configured for rotational attachment to the locking hub, the feeding tube assembly including a protrusion insertable into the annular recess and connected to a release feature such that activation of the release feature detaches the feeding tube assembly from the locking hub;

a base element, including a distally extending stem configured for insertion into a gastrostomy tube;

a one way valve positioned in a lumen of the base element; and

a compression structure, including one or more engagement features configured to engage the one or more locking elements, the gastrostomy tube compressed between the compression structure and the stem when the one or more engagement features engage the one or more locking elements.

* * * * *